

8/21/00 2:01 pm

Notification Tracking Sheet

=====
Bp number: 00-231-07n
=====

App number: 2000-566XRAB Begin movement: 9/16/00
Received: 8/18/00 End movement: 9/16/01
Institution: Monsanto Begin release: 9/16/00
Recipient: Wheat End release: 9/16/01
Status: Pending Acre: 5.00
Effective date: 9/17/00 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)** Fax: 636-737-7085
=====

- | | Initial | Date |
|--|-----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [8/21/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>AMK</i>]* | [8/22/2000] |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLR</i>] | [8/24/00]* |
| 4. <input type="checkbox"/> State response | | |

- | | O/d | Loc | Site | Reg | | |
|------------|--------|-----|------|------|---|----------|
| Interstate | *Dest* | KS | * | *SCR | * | [] |
| Interstate | *Dest* | WA | * | *WR | * | [] |
| Interstate | *Orig* | KS | * | *SCR | * | |
| Interstate | *Orig* | WA | * | *WR | * | |
| Release | * | *WA | * | 1*WR | * | [] |
-
- | | | |
|--|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [8/22/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLR</i>] | [9/29/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLR</i>] | [10/2/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-566XRAB

August 17, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-231-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-566XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

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Monsanto Reference ID

2000-566XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMcVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-566XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/5 -- (b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

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Monsanto Reference ID

2000-566XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location.

ORIGIN:
KS, WA

DESTINATION:
KS, WA

Ship From:

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

WA

*[(b) (4) Walla Walla County/Province,
WA, (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-566XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

WA

*[(b) (4) Walla Walla County/Province,
WA, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-566XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[REDACTED] (b) (4) Walla Walla County/Province,
WA, U.S.A., 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
[REDACTED] (b) (4), (b) (6), (b) (7)(C) WA [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

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CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-566XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 17, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-566XRAB

Permit Unit

August 17, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-231-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-566XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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636/737-7085

E-Mail

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

WA (1)

WA

[CBI Deleted] -- Walla Walla County/Province, WA, U.S.A., 5 acres

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CBI-DELETED

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CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-566XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 17, 2000

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USDA, APHIS, PPQ, BSS

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4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-566XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-566XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP7-CP4 --

(b) (4)

CBI

(b) (4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-566XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

* [REDACTED] (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) [REDACTED] KS (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

WA

* [REDACTED] (b) (4) Walla Walla County/Province,
WA (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C) [REDACTED]
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) [REDACTED]

] - CBI

Ship To:

KS

* [REDACTED] (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-566XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[(b) (4) Walla Walla County/Province,
WA (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-566XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4) Walla Walla County/Province,
WA, U.S.A., 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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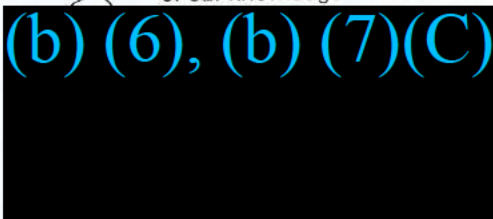
Monsanto Reference ID

2000-566XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 17, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-566XRAB

Permit Unit

August 17, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-231-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-566XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-566XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Walla Walla County/Province, WA, U.S.A., 5 acres

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CBI-DELETED

Monsanto Reference ID

2000-566XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 17, 2000

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 21, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-231-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-231-07n	Applicant #:	2000-566XRAB
Received:	August 18, 2000	Effective:	September 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006367

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

August 21, 2000

Dear Mr. Wessels:

Enclosed is notification 00-231-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-231-07n	Applicant #:	2000-566XRAB
Received:	August 18, 2000	Effective:	September 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006368



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

August 21, 2000

Dear Mr. Wessels:

Enclosed is notification 00-231-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-231-07n	Applicant #:	2000-566XRAB
Received:	August 18, 2000	Effective:	September 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 8/25/00

State: WA

Rptloc01/R4



September 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after September 29, 2000.**

Interstate movement and Release
Notification no. 00-231-07n (2000-566XRAB)
Regulated article - Wheat
Destinations - Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-231-07n

OR120018_BR_006370

Confirmation Report-Memory Send

Time : Sep-29-00 04:38pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 582
Date : Sep-29 04:36pm
To : 916367377085
Document Pages : 01
Start time : Sep-29 04:37pm
End time : Sep-29 04:38pm
Pages sent : 01
Job number : 582

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

September 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 29, 2000.

Interstate movement and Release
Notification no. 00-231-07n (2000-566XRB)
Regulated article - Wheat
Destinations - Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006371

2000 Wheat Field Trial Report
USDA # 00-231-07n Monsanto # 2000-566XRAB

May 13, 2002

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Walla Walla

State
WA (NOT PLANTED)

8/21/00 2:01 pm

Notification Tracking Sheet

=====
Bp number: 00-231-08n
=====

App number: 2000-567XRAB Begin movement: 9/16/00
Received: 8/18/00 End movement: 9/16/01
Institution: Monsanto Begin release: 9/16/00
Recipient: Wheat End release: 9/16/01
Status: Pending Acre: 5.00
Effective date: 9/17/00 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>aid</i>]	[8/21/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>AMK</i>]*	[8/22/2000]
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i>	[<i>KLN</i>]	[8/24/00]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*	[]
Interstate	*Orig*	KS	*	*SCR	*	[]
Release	*	*KS	*	1*SCR	*	[]

=====

5. <input checked="" type="checkbox"/> Enter genes into database	[<i>aid</i>]	[8/22/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[<i>KLN</i>]	[9/29/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>KLN</i>]	[10/2/00]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-567XRAB

August 17, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-231-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-567XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-567XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-567XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-567XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location

ORIGIN:

KS

DESTINATION:

KS

Ship From:

KS

*[(b) (4) Harvey County/Province, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

KS

*[(b) (4) Harvey County/Province, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-567XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-567XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

[(b) (4) (b) (4) Harvey County/Province, KS, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

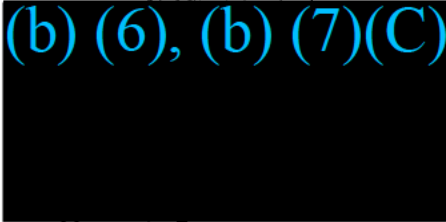
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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 17, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-567XRAB

Permit Unit

August 17, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-231-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-567XRAB

3. Applicant/Responsible Party

(b) (4), (b) (6), (b) (7)(C)

Phone

(b) (4), (b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (4), (b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location

ORIGIN:

KS

DESTINATION:

KS

Ship From:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

[CBI Deleted] -- Harvey County/Province, KS, USA, 5 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

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(b) (4), (b) (6), (b) (7)(C)



Monsanto Company

August 17, 2000

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September 16, 2000 - September 16, 2001

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(b)(4)

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(b)(4)

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CONFIDENTIAL

Monsanto Reference ID
2000-567XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/5 --

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 --

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

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Ship From:

KS

*[(b)(4) Harvey County/Province, KS (b)(4) USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

*[(b)(4) Sedgwick County/Province, KS (b)(4) USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,

] - CBI

Ship To:

KS

*[(b)(4) Harvey County/Province, KS (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-567XRAB

CONTACT: [REDACTED]

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

KS, [REDACTED]

(b) (4), (b) (6), (b) (7)(C)

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(b)(4)

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(b) (4), (b) (6), (b) (7)(C)

USA,

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file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 21, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-231-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-231-08n	Applicant #:	2000-567XRAB
Received:	August 18, 2000	Effective:	September 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS		
Release destination:	KS		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006403

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~~CBI-DELETED~~

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-567XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 17, 2000

00-231-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-567XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium species, strain~~ CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium species, strain~~ CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location

ORIGIN:

KS

DESTINATION:

KS

Ship From:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

Ship To:

KS

[CBI Deleted] -- *Harvey County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-567XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

[CBI Deleted] -- Harvey County/Province, KS, USA, 5 acres

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-567XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 17, 2000

September 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after September 29, 2000.**

Interstate movement and Release
Notification no. 00-231-08n (2000-567XRAB)
Regulated article - Wheat
Destination - Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-231-08n

OR120018_BR_006411

Not a FOIA Deletion

Confirmation Report-Memory Send

Time : Sep-29-00 04:37pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 581
Date : Sep-29 04:36pm
To : 916367377085
Document Pages : 01
Start time : Sep-29 04:36pm
End time : Sep-29 04:37pm
Pages sent : 01
Job number : 581

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

September 29, 2000

(b) (6), (b) (7)(C)

700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 29, 2000.

Interstate movement and Release
Notification no. 00-231-08n (2000-567XRAB)
Regulated article - Wheat
Destination - Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Ratmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:
T. Sim, Kansas State Board of Agric., Topeka, KS
D. DeWeese, PPQ, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006413

MONSANTO



April 11, 2002

Attn: Mary Jackson
Regulatory Analyst
Animal and Plant Inspection Services
Biotechnology, Biologics, and Environmental Protection
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737-1237

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Reference: Submission of Final Test Reports

Dear Mary,

The following USDA field releases have been completed and we are now submitting final reports required by the notifications. Please find the final reports for the following USDA notifications enclosed.

Monsanto ID#	USDA #	Crop
2000-613XRAB	00-262-05n	Wheat
2000-567XRAB	00-231-08n	Wheat

Sincerely,

(b) (6), (b) (7)(C)



OR120018_BR_006414

2000 Wheat Field Trial Report
USDA # 00-231-08n Monsanto # 2000-567XRAB

Biotech Field Compliance Team
October 18, 2001
Monsanto Company

Location	County	State
Site 1	Harvey	KS

Site 1

Planting Date: October 7, 2000

Harvest Date: June 28, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Site 1

Planting Date: November 13, 2000

Destruct Date: June 12, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Method of Devitalization or Final Disposition of Plot after Harvesting: [CBI deleted]

2000 Wheat Field Trial Report
USDA # 00-231-08n Monsanto # 2000-567XRAB

Biotech Field Compliance Team
October 18, 2001
Monsanto Company

Location

Site 1

County

Harvey

State

KS

Site 1

Planting Date: October 7, 2000

Harvest Date: June 28, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: (b) (4)
(b) (4)

Disposition of the Harvested Material: (b) (4)
(b) (4)

Site 1

Planting Date: November 13, 2000

Destruct Date: June 12, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)
(b) (4)

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Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics:

(b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:

(b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot after Harvesting:

(b) (4)

(b) (4)

8/21/00 2:01 pm

Notification Tracking Sheet

=====

Bp number: 00-231-09n

=====

App number: 2000-568XRAB

Received: 8/18/00

Institution: Monsanto

Recipient: Wheat

Status: Pending

Effective date: 9/17/00

Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Begin movement: 9/16/00

End movement: 9/16/01

Begin release: 9/16/00

End release: 9/16/01

Acre: 5.00

CBI status: CBI

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[aid]	[8/21/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[AMK]*	[8/21/2000]
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLO]	[8/24/00]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg
Interstate *Dest*KS *				*SCR *
Interstate *Orig*KS *				*SCR *
Release * *KS *				1*SCR *

[]	[]
[]	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[aid]	[8/22/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[KLO]	[9/29/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[KLO]	[10/2/00]

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-568XRAB

August 17, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-231-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-568XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I/2 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I/5 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- (b)(4)

CBI

Gene: CTP2-CP4 -- (b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- (b)(4)

CBI

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Monsanto Reference ID

2000-568XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS

DESTINATION:

KS

Ship From:

KS

*[(b)(4)] Sedgwick County/Province, KS, (b)(4) USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,

] - CBI

*[(b)(4)] Ottawa County/Province, KS, (b)(4) U.S.A.

CONTACT:

(b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

Ship To:

KS

*[(b)(4)] Sedgwick County/Province, KS, (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b)(4) Ottawa County/Province, KS, (b)(4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

[(b)(4)] Ottawa County/Province, KS, U.S.A., 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-568XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 17, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-568XRAB

August 17, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-231-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-568XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-568XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-568XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-568XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS

DESTINATION:

KS

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

[CBI Deleted] -- *Ottawa County/Province, KS, U.S.A.

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-568XRAB

[CBI Deleted] -- *Ottawa County/Province, KS, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-568XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

[CBI Deleted] -- Ottawa County/Province, KS, U.S.A., 5 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

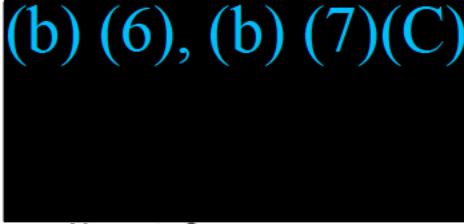
Monsanto Reference ID

2000-568XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 17, 2000

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID

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Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

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4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b)(4)

CBI

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GENE OF INTEREST

Promoter: CMP3/l5 --

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 --

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS

DESTINATION:

KS

Ship From:

KS

* [REDACTED] (b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONTACT: [REDACTED] (b)(4), (b)(6), (b)(7)(C) KS, [REDACTED] (b)(4), (b)(6), (b)(7)(C) USA,

] - CBI

* [REDACTED] (b)(4) Ottawa County/Province, KS, (b)(4) U.S.A.

CONTACT: [REDACTED] (b)(4), (b)(6), (b)(7)(C) KS, [REDACTED] (b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

Ship To:

KS

* [REDACTED] (b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b)(4) Ottawa County/Province, KS, (b)(4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-568XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

KS (1)

KS

[(b)(4) Ottawa County/Province, KS, U.S.A., 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b)(4), (b)(6), (b)(7)(C) KS (b)(4), (b)(6), (b)(7)(C) U.S.A. (b)(4), (b)(6), (b)(7)(C)

] - CBI

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CONFIDENTIAL

Monsanto Reference ID
2000-568XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

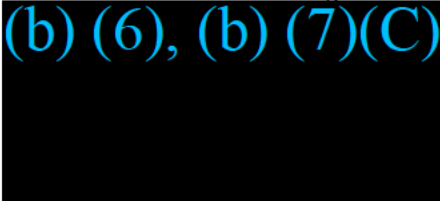
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
August 17, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID

2000-568XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

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00-231-09n

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MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-568XRAB

designation of transformed line: 33512

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Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [~~CBI Deleted~~]

CBI

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GENE OF INTEREST

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CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~agrobacterium~~ species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-568XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS

DESTINATION:

KS

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

[CBI Deleted] -- *Ottawa County/Province, KS, U.S.A.

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

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CBI-DELETED

Monsanto Reference ID
2000-568XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108

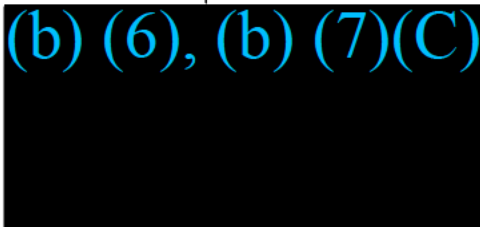
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of my knowledge. If any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
August 17, 2000

September 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after September 29, 2000.**

Interstate movement and Release
Notification no. 00-231-09n (2000-568XRAB)
Regulated article - Wheat
Destination - Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-231-09n

OR120018_BR_006453

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 21, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-231-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-231-09n	Applicant #:	2000-568XRAB
Received:	August 18, 2000	Effective:	September 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS		
Release destination:	KS		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006454

Confirmation Report-Memory Send

Time : Sep-29-00 04:35pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 580
Date : Sep-29 04:33pm
To : 916367377085
Document Pages : 01
Start time : Sep-29 04:34pm
End time : Sep-29 04:35pm
Pages sent : 01

Job number : 580

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

(b) (6), (b) (7)(C)

September 29, 2000

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 29, 2000.

Interstate movement and release
Notification no. 00-231-09n (2000-568XRAB)
Regulated article - Wheat
Destination - Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

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Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
D. DeWeese, PPQ, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006455

2000 Wheat Field Trial Report
USDA # 00-231-09n Monsanto # 2000-568XRAB

Biotech Field Compliance Team
October 17, 2001
Monsanto Company

Location

Site 1

County

Ottawa

State

KS

Site 1

Planting Date: October 12, 2000

Destruct Date: June 25, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics:

(b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:

(b) (4)

(b) (4)

Not a FOIA Deletion

2000 Wheat Field Trial Report
USDA # 00-231-09n Monsanto # 2000-568XRAB

Biotech Field Compliance Team
October 17, 2001
Monsanto Company

Location	County	State
Site 1	Ottawa	KS

Site 1

Planting Date: October 12, 2000

Destruct Date: June 25, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

8/21/00 2:01 pm

Notification Tracking Sheet

=====

Bp number: 00-231-10n

=====

App number: 2000-569XRAB
 Received: 8/18/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 9/17/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person:
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C)
 Begin movement: 9/16/00
 End movement: 9/16/01
 Begin release: 9/16/00
 End release: 9/16/01
 Acre: 10.00
 CBI status: CBI

Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ajb]	[8/21/2000]
2. <input type="checkbox"/> Review by biotechnologist	[AMK]*	[8/22/2000]
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KZLO]	[8/24/00]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*SCR *
Interstate	*Dest*	OK	*SCR *
Interstate	*Orig*	KS	*SCR *
Interstate	*Orig*	OK	*SCR *
Release	*	*OK	* 2*SCR *

5. <input checked="" type="checkbox"/> Enter genes into database	[ajb]	[8/22/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[KZLO]	[10/3/00]*
7. <input type="checkbox"/> Enter final data into database	[KZLO]	[10/5/00]

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-569XRAB

Permit Unit

August 17, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-231-10n

1. USDA Reference Number

2. Applicant Reference Number 2000-569XRAB

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St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

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Monsanto Reference ID

2000-569XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Promoter: CMP3/l5 -- (b) (4)

CBI

(b) (4)

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-569XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- (b) (4)

CBI

Gene: CTP7-CP4 - (b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- (b) (4)

CBI

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Monsanto Reference ID

2000-569XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location

ORIGIN:

KS, OK

DESTINATION:

KS, OK

Ship From:

KS

*[(b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

OK

*[(b) (4) Payne County/Province, OK, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) OK, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-569XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

OK

*] (b) (4) Payne County/Province, OK,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OK, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID

2000-569XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OK (2)

OK

(b) (4)

Payne County/Province, OK, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

OK,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

Payne County/Province, OK, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

OK,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID

2000-569XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

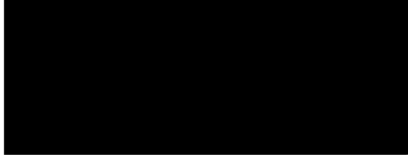
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 17, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-569XRAB

Permit Unit

August 17, 2000

USDA, APHIS, PPQ, BSS

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Riverdale, MD 27037

00-231-10n

1. USDA Reference Number

2. Applicant Reference Number 2000-569XRAB

3. Applicant/Responsible Party

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Phone

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700 Chesterfield Parkway North

St. Louis

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4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-569XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

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CBI-DELETED

Monsanto Reference ID

2000-569XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

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CBI

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Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-569XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location

ORIGIN:

KS, OK

DESTINATION:

KS, OK

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

OK

[CBI Deleted] -- *Payne County/Province, OK, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

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CBI-DELETED

Monsanto Reference ID

2000-569XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OK (2)

OK

[CBI Deleted] -- Payne County/Province, OK, USA, 5 acres

[CBI Deleted] -- Payne County/Province, OK, USA, 5 acres

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CBI-DELETED

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(b) (6), (b) (7)(C)



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August 17, 2000

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designation of transformed line: 33512

Constructs: PV-TXGT12

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Promoter: CMP 3/15 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- [

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-569XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
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ORIGIN:
KS, OK

DESTINATION:
KS, OK

Ship From:

KS

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

OK

* (b) (4) Payne County/Province, OK, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) OK, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

KS

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-569XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

OK

(b) (4) USA (b) (4) Payne County/Province, OK,

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OK (b) (4), (b) (6), (b) (7)(C) USA,

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Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OK (2)

OK

[(b) (4) Payne County/Province, OK, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OK, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

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RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OK, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

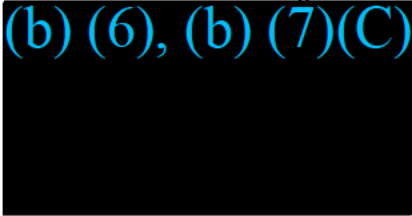
Monsanto Reference ID

2000-569XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 17, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-569XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 17, 2000

00-231-10n

1. USDA Reference Number

2. Applicant Reference Number 2000-569XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-569XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium species~~ strain .
CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium species~~ strain .
CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-569XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-569XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pound of wheat seed to and from each location

ORIGIN:

KS, OK

DESTINATION:

KS, OK

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

OK

[CBI Deleted] -- *Payne County/Province, OK, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-569XRAB

OK

[CBI Deleted] -- *Payne County/Province, OK, USA

CBI-DELETED

Monsanto Reference ID

2000-569XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OK (2)

OK

[CBI Deleted] -- Payne County/Province, OK, USA, 5 acres

[CBI Deleted] -- Payne County/Province, OK, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2000-569XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

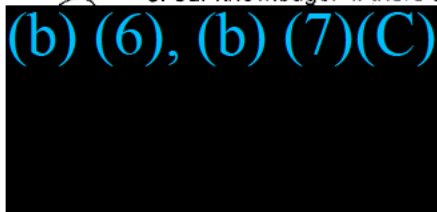
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 17, 2000

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 21, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-231-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-231-10n	Applicant #:	2000-569XRAB
Received:	August 18, 2000	Effective:	September 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OK		
Release destination:	OK		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006496



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Charles R. Pfelffer, Program Manager
Plant Industry Division
Oklahoma State Department of Agriculture
P.O. Box 528804
Oklahoma City, OK 73152-8804

August 21, 2000

Dear Mr. Pfelffer:

Enclosed is notification 00-231-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-231-10n	Applicant #:	2000-569XRAB
Received:	August 18, 2000	Effective:	September 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OK		
Release destination:	OK		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: CHARLES R. PFELFFER

Signature: (b) (6), (b) (7)(C)

Date: 08/25/00

State: OKLAHOMA

Rptloc01/R4



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An Equal Opportunity Employer

SEP 29 2000

OR120018_BR_006497

file copy

Mr. Charles R. Pfelffer, Program Manager
Plant Industry Division
Oklahoma State Department of Agriculture
P.O. Box 528804
Oklahoma City, OK 73152-8804

August 21, 2000

Dear Mr. Pfelffer:

Enclosed is notification 00-231-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-231-10n	Applicant #:	2000-569XRAB
Received:	August 18, 2000	Effective:	September 17, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS OK		
Release destination:	OK		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

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Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006498

October 3, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after October 3, 2000.**

Interstate movement and Release
Notification no. 00-231-10n (2000-569XRAB)
Regulated article - Wheat
Destinations - Kansas, Oklahoma

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
C. Pfelffer, Oklahoma State Dept. of Agric., Oklahoma City, OK
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-231-10n

OR120018_BR_006499

Not a FOIA Deletion

Confirmation Report-Memory Send

Time : Oct-03-00 03:39pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 616
Date : Oct-03 03:38pm
To : 916367377085
Document Pages : 01
Start time : Oct-03 03:38pm
End time : Oct-03 03:39pm
Pages sent : 01
Job number : 616

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

(b) (6), (b) (7)(C)

October 3, 2000

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 3, 2000.

Interstate movement and Release
Notification no. 00-231-10n (2000-569XRAB)
Regulated article - Wheat
Destinations - Kansas, Oklahoma

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

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Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
C. Pfeiffer, Oklahoma State Dept. of Agric., Oklahoma City, OK
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_006501

CONFIDENTIAL

**2000 Wheat Field Test Report
USDA #00-231-10n Monsanto #2000-569XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147304818	Payne County	OK
2147304817	Payne County	OK

Payne County/OK (2147304818)

(b) (4)

(b) (4)

Payne County/OK (2147304817)

(b) (4)

(b) (4)

CBI-DELETED

**2000 Wheat Field Test Report
USDA #00-231-10n Monsanto #2000-569XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147304818	Payne County	OK
2147304817	Payne County	OK

Payne County/OK (2147304818)

Planting Date: 11/17/2000

Harvest Date: 06/19/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Payne County/OK (2147304817)

Planting Date: 11/21/2000

Harvest Date: 06/19/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

8/21/00 2:01 pm

Notification Tracking Sheet

Bp number: 00-234-02n

App number: 2000-570XRAB
 Received: 8/21/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 9/20/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person:
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C)
 Begin movement: 9/16/00
 End movement: 9/16/01
 Begin release: 9/16/00
 End release: 9/16/01
 Acre: 7.00
 CBI status: CBI
 Fax: 636-737-7085

	Initial	Date
1. [✓] Assign Bp number and initial data entry	[ajd]	[8/21/2000]
2. [✓] Review by biotechnologist	[gmk]*	[8/22/2000]*
3. [✓] Letter of notification to State Fed-ex	[KLO]	[8/24/00]*
4. [] State response		

O/d	Loc	Site	Reg
Interstate	*Dest*CO	*	*WR *
Interstate	*Dest*ID	*	*WR *
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*OK	*	*SCR *
Interstate	*Dest*WA	*	*WR *
Interstate	*Orig*CO	*	*WR *
Interstate	*Orig*ID	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*OK	*	*SCR *
Interstate	*Orig*WA	*	*WR *
Release	*CO	*	1*WR *
Release	*ID	*	1*WR *
Release	*KS	*	2*SCR *
Release	*OK	*	1*SCR *
Release	*WA	*	1*WR *

5. [✓] Enter genes into database	[ajd]	[8/22/2000]
6. [✓] Letter of <u>acknowledgement</u> /denial/withdraw	[KLO]	[10/3/00]*
7. [✓] Enter final data into database	[KLO]	[10/5/00]

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

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FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2000-570XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 17, 2000

00-234-02n

1. USDA Reference Number

2. Applicant Reference Number 2000-570XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite and various breeding lines.

CONFIDENTIAL

Monsanto Reference ID

2000-570XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-570XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/45 -- [

(b) (4)

CBI

(b) (4)

Gene: CTP7-CP4 --

(b) (4)

CBI

(b) (4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

(b) (4)

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Monsanto Reference ID

2000-570XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:

CO, ID, KS, OK, WA

DESTINATION:

CO, ID, KS, OK, WA

Ship From:

CO

*[(b) (4) Arapaho County/Province, CO, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

ID

(b) (4)

Latah County/Province, ID, (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

KS

*[(b) (4) Ellis
County/Province, KS, (b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-570XRAB

*[(b) (4) , Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) , KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

OK

*[(b) (4) Payne County/Province, OK,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OK, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[(b) (4) Walla Walla County/Province,
WA, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

CO

*[(b) (4) Arapaho County/Province, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) , CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-570XRAB

ID

*[(b) (4)] Latah County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

*[(b) (4)] Ellis
County/Province, KS, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

OK

*[(b) (4)] Payne County/Province, OK,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OK, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID

2000-570XRAB

WA

*[(b) (4) Walla Walla County/Province,
WA, (b) (4), U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID

2000-570XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1), ID (1), KS (2), OK (1), WA (1)

CO

(b) (4)

Yuma County/Province, CO, 1 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

CO,

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

ID

(b) (4)

Latah County/Province, ID, U.S.A., 1 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

ID,

(b) (4), (b) (6), (b) (7)(C)

U.S.A.,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

(b) (4)

County/Province, KS, 1 acres.

Ellis

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

KS,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

Sedgwick County/Province, KS, USA, 2 acres.

CONFIDENTIAL

Monsanto Reference ID

2000-570XRAB

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

OK

(b) (4) Payne County/Province, OK, USA, 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) OK, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

(b) (4) Walla Walla County/Province, WA, U.S.A., 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2000-570XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 17, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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Monsanto Reference ID

2000-570XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 17, 2000

00-234-02n

1. USDA Reference Number

2. Applicant Reference Number 2000-570XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite and various breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:

CO, ID, KS, OK, WA

DESTINATION:

CO, ID, KS, OK, WA

Ship From:

CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Ellis County/Province, KS

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

OK

[CBI Deleted] -- *Payne County/Province, OK, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

Ship To:

CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Ellis County/Province, KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

OK

[CBI Deleted] -- *Payne County/Province, OK, USA

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1), ID (1), KS (2), OK (1), WA (1)

CO

[CBI Deleted] -- Yuma County/Province, CO, 1 acres

ID

[CBI Deleted] -- Latah County/Province, ID, U.S.A., 1 acres

KS

[CBI Deleted] -- Ellis County/Province, KS, 1 acres

[CBI Deleted] -- Sedgwick County/Province, KS, USA, 2 acres

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

OK

[CBI Deleted] -- Payne County/Province, OK, USA, 1 acres

WA

[CBI Deleted] -- Walla Walla County/Province, WA, U.S.A., 1 acres

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CBI-DELETED

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FAX (636) 737-7083

<http://www.monsanto.com>

Monsanto Reference ID

2000-570XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 17, 2000

MONSANTO

Food · Health · Hope



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2000-570XRAB

August 17, 2000

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

00-234-02n

1. USDA Reference Number
2. Applicant Reference Number 2000-570XRAB
3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

September 16, 2000 - September 16, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite and various breeding lines.

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1000 pounds of wheat seed to and from each location.

ORIGIN:

CO, ID, KS, OK, WA

DESTINATION:

CO, ID, KS, OK, WA

Ship From:

CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Ellis County/Province, KS

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

OK

[CBI Deleted] -- *Payne County/Province, OK, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

Ship To:

CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Ellis County/Province, KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

OK

[CBI Deleted] -- *Payne County/Province, OK, USA

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1), ID (1), KS (2), OK (1), WA (1)

CO

[CBI Deleted] -- Yuma County/Province, CO, 1 acres

ID

[CBI Deleted] -- Latah County/Province, ID, U.S.A., 1 acres

KS

[CBI Deleted] -- Ellis County/Province, KS, 1 acres

[CBI Deleted] -- Sedgwick County/Province, KS, USA, 2 acres

CBI-DELETED

Monsanto Reference ID

2000-570XRAB

OK

[CBI Deleted] -- Payne County/Province, OK, USA, 1 acres

WA

[CBI Deleted] -- Walla Walla County/Province, WA, U.S.A., 1 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2000-570XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 17, 2000

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

August 21, 2000

Dear Mr. Yergert:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-234-02n	Applicant #:	2000-570XRAB
Received:	August 21, 2000	Effective:	September 20, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID KS OK WA		
Release destination:	CO ID KS OK WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006544

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

August 21, 2000

Dear Dr. Vega:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-234-02n	Applicant #:	2000-570XRAB
Received:	August 21, 2000	Effective:	September 20, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID KS OK WA		
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Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006545

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 21, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-234-02n	Applicant #:	2000-570XRAB
Received:	August 21, 2000	Effective:	September 20, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID KS OK WA		
Release destination:	CO ID KS OK WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006546

file copy

Mr. Charles R. Pfelffer, Program Manager
Plant Industry Division
Oklahoma State Department of Agriculture
P.O. Box 528804
Oklahoma City, OK 73152-8804

August 21, 2000

Dear Mr. Pfelffer:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-234-02n	Applicant #:	2000-570XRAB
Received:	August 21, 2000	Effective:	September 20, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID KS OK WA		
Release destination:	CO ID KS OK WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006547

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

August 21, 2000

Dear Mr. Wessels:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-234-02n	Applicant #:	2000-570XRAB
Received:	August 21, 2000	Effective:	September 20, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID KS OK WA		
Release destination:	CO ID KS OK WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006548



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Mitch Vergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

August 21, 2000

Dear Mr. Vergert:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-234-02n Applicant #: 2000-570XRAB
Received: August 21, 2000 Effective: September 20, 2000
Institution: Monsanto Recipient: Wheat
Interstate destination: CO ID KS OK WA
Release destination: CO ID KS OK WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Vergert

Signature: (b) (6), (b) (7)(C)

Date: August 29, 2000

State: Colorado

Rptloc01/R4



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AUG 29 2000

OR120018_BR_006549



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

AUG 25 2000

PLANT INDUSTRIES

August 21, 2000

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

Dear Dr. Vega:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-234-02n	Applicant #:	2000-570XRAB
Received:	August 21, 2000	Effective:	September 20, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID KS OK WA		
Release destination:	CO ID KS OK WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

(b) (6), (b) (7)(C)

Date: Aug. 25, 2000

State: IDAHO

Rptloc01/R4



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An Equal Opportunity Employer

AUG 29 2000

OR120018_BR_006550



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Charles R. Pfelffer, Program Manager
Plant Industry Division
Oklahoma State Department of Agriculture
P.O. Box 528804
Oklahoma City, OK 73152-8804

August 21, 2000

Dear Mr. Pfelffer:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-234-02n	Applicant #:	2000-570XRAB
Received:	August 21, 2000	Effective:	September 20, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID KS OK WA		
Release destination:	CO ID KS OK WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: CHARLES R. PFELFFER

Signature: (b) (6), (b) (7)(C)

Date: 25 Aug 00

State: Oklahoma

Rptloc01/R4



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An Equal Opportunity Employer

SEP 29 2000

OR120018_BR_006551



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

August 21, 2000

Dear Mr. Wessels:

Enclosed is notification 00-234-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number	00-234-02n	Applicant #:	2000-570XRAB
Received:	August 21, 2000	Effective:	September 20, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID KS OK WA		
Release destination:	CO ID KS OK WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 8/25/00

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

AUG 29 2000

OR120018_BR_006552

October 3, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 3, 2000.

Interstate movement and Release

Notification no. 00-234-02n (2000-570XRAB)

Regulated article - Wheat

Destinations - Colorado, Idaho, Kansas, Oklahoma, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
C. Pfelffer, Oklahoma State Dept. of Agric., Oklahoma City, OK
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-234-02n

OR120018_BR_006553

Confirmation Report-Memory Send

Time : Oct-03-00 03:38pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 615
Date : Oct-03 03:37pm
To : 916367377085
Document Pages : 01
Start time : Oct-03 03:37pm
End time : Oct-03 03:38pm
Pages sent : 01
Job number : 615

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

October 3, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 3, 2000.

Interstate movement and Release

Notification no. 00-234-02n (2000-570)GRAB

Regulated article - Wheat

Destinations - Colorado, Idaho, Kansas, Oklahoma, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Vergert, Colorado Dept. of Agric., Lakewood, CO
R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
C. Pfeiffer, Oklahoma State Dept. of Agric., Oklahoma City, OK
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPO, WR, Sacramento, CA
D. DeWeese, PPO, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006554

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-234-02n Monsanto #2000-570XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
7414	Yuma County	CO
-1782333410	Latah County	ID
8190	Ellis County	KS
7742	Sedgwick County	KS
2147304816	Payne County	OK
2066639202	Walla Walla County	WA

Yuma County/CO (7414)

(b)(4)

(b)(4)

Latah County/ID (-1782333410)

(b)(4)

Ellis County/KS (8190)

(b)(4)

(b)(4)

Sedgwick County/KS (7742)

(b)(4)

(b)(4)

Payne County/OK (2147304816)

(b)(4)

(b)(4)

Walla Walla County/WA (2066639202)

(b)(4)

(b)(4)

CBI-DELETED

**2000 Wheat Field Test Report
USDA #00-234-02n Monsanto #2000-570XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
7414	Yuma County	CO
-1782333410	Latah County	ID
8190	Ellis County	KS
7742	Sedgwick County	KS
2147304816	Payne County	OK
2066639202	Walla Walla County	WA

Yuma County/CO (7414)

Planting Date: 10/11/2000

Harvest Date: 07/12/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Latah County/ID (-1782333410)

Planting Date: 10/24/2000

Harvest Date: 09/07/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Ellis County/KS (8190)

Planting Date: 10/10/2000

Harvest Date: 07/02/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Sedgwick County/KS (7742)

Planting Date: 10/11/2000

Harvest Date: 06/25/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Payne County/OK (2147304816)

Planting Date: 11/17/2000

Harvest Date: 06/19/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Walla Walla County/WA (2066639202)

Planting Date: 10/13/2000

Harvest Date: 07/11/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

8/24/00 1:26 pm

Notification Tracking Sheet

=====

Bp number: 00-236-01n

=====

App number: 2000-536XRAB
 Received: 8/23/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 9/22/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: 636-737-6032
 Begin movement: 9/09/00
 End movement: 9/09/01
 Begin release: 9/09/00
 End release: 9/09/01
 Acre: 5.00
 CBI status: CBI
 Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ajd]	[8/24/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[LMK]*	[8/24/2000]
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLD]	[8/25/00*]
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg
Interstate	*Dest*	AZ	*	*WR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Orig*	AZ	*	*WR *
Interstate	*Orig*	MO	*	*SCR *
Release	*	AZ	*	1*WR *

[]	[]
[]	[]
[]	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[ajd]	[8/24/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement/denial/withdraw</u>	[ajd]	[9/21/2000]
7. <input checked="" type="checkbox"/> Enter final data into database	[ajd]	[9/21/2000]

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Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-536XRAB

August 10, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-236-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-536XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 09, 2000 - September 09, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar variety: Bobwhite

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Monsanto Reference ID

2000-536XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-536XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

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Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S0317, TA S0621, TA S0635, TA S1081, TA S2520, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [REDACTED]

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S9717, TA S10031

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MB4

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3'

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S9240, TA S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S7535, TA S7890, TA S9512, TA S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

GENE OF INTEREST

Promoter: 1Ax1 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-536XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-536XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1)

AZ

(b) (4)

Yuma County/Province, AZ, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) Yuma, AZ

(b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID

2000-536XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 10, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-536XRAB

August 10, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-236-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-536XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 09, 2000 - September 09, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar variety: Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S0317, TA S0621, TA S0635, TA S1081, TA S2520, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S9717, TA S10031

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S9240, TA S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S7535, TA S7890, TA S9512, TA S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S11112, TA S11478

Constructs: PV-TXHT3

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMoVa/18 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 2000kg of wheat seeds and leaf tissues to and from each location.

ORIGIN:
AZ, MO

DESTINATION:
AZ, MO

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1)

AZ

[CBI Deleted] -- Yuma County/Province, AZ, 5 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

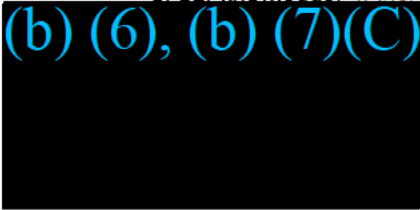
Monsanto Reference ID

2000-536XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 10, 2000

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

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Monsanto Reference ID

2000-536XRAB

August 10, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-236-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-536XRAB

3. Applicant/Responsible Party

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 09, 2000 - September 09, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar variety: Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 -- [

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [

(b)(4)

(b)(4)

CBI

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Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S0317, TA S0621, TA S0635, TA S1081, TA S2520, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' --

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S9717, TA S10031

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 -- [REDACTED]

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [REDACTED]

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [REDACTED]

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S9240, TA S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S7535, TA S7890, TA S9512, TA S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

GENE OF INTEREST

Promoter: 1Ax1 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000kg of wheat seeds and leaf tissues to and from each location.

ORIGIN:

AZ, MO

DESTINATION:

AZ, MO

Ship From:

AZ

*[(b)(4) Yuma County/Province, AZ, (b)(4)

CONTACT: (b)(6), (b)(4), (b)(7)(C) AZ,
(b)(6), (b)(4), (b)(7)(C)

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b)(6), (b)(4), (b)(7)(C) MO,
(b)(6), (b)(4), (b)(7)(C) U.S.A., (b)(6), (b)(4), (b)(7)(C)

] - CBI

Ship To:

AZ

*[(b)(4) Yuma County/Province, AZ, (b)(4)

CONFIDENTIAL

Monsanto Reference ID

2000-536XRAB

CONTACT: (b) (6), (b) (4), (b) (7)(C) AZ,
(b) (6), (b) (4), (b) (7)(C)

] - CBI

MO

* (b)(4) St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT: (b) (6), (b) (4), (b) (7)(C) MO,
(b) (6), (b) (4), (b) (7)(C) U.S.A., (b) (6), (b) (4), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-536XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1)

AZ

[REDACTED] (b)(4) Yuma County/Province, AZ, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (4), (b) (7)(C)
(b) (6), (b) (4), (b) (7)(C) AZ, [REDACTED] (b) (6), (b) (4), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2000-536XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

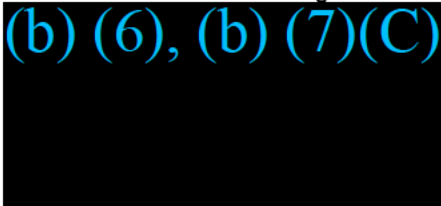
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
August 10, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

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Monsanto Reference ID

2000-536XRAB

August 10, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-236-01n

1. USDA Reference Number

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3. Applicant/Responsible Party

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 09, 2000 - September 09, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar variety: Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CPT.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S0317, TA S0621, TA S0635, TA S1081, TA S2520, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [. CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S9717, TA S10031

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium species, strain~~ CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium species, strain~~ CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S9240, TA S9719

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium~~ species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S7535, TA S7890, TA S9512, TA S10430

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium species, strain~~ CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

designation of transformed line: TA S11112, TA S11478

Constructs: PV-TXHT3

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium~~ species, strain ~~CP4~~.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMoVa/18 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an ~~Agrobacterium~~ species, strain ~~CP4~~.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000kg of wheat seeds and leaf tissues to and from each location.

ORIGIN:

AZ, MO

DESTINATION:

AZ, MO

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-536XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1)

AZ

[CBI Deleted] -- Yuma County/Province, AZ, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID
2000-536XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, Missouri 63198

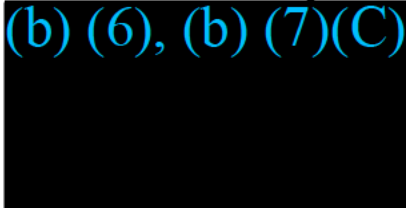
PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
August 10, 2000

file copy

Dr. Scott Sobey, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

August 24, 2000

Dear Dr. Sobey:

Enclosed is notification 00-236-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-236-01n	Applicant #:	2000-536XRAB
Received:	August 23, 2000	Effective:	September 22, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006621

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 24, 2000

Dear Mr. Brown:

Enclosed is notification 00-236-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-236-01n	Applicant #:	2000-536XRAB
Received:	August 23, 2000	Effective:	September 22, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006622



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Scott Sobey, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

August 24, 2000

Dear Dr. Sobey:

Enclosed is notification 00-236-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-236-01n
Received: August 23, 2000
Institution: Monsanto
Interstate destination: AZ MO
Release destination: AZ

Applicant #: 2000-536XRAB
Effective: September 22, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is noted under 7 CFR 340.3 (c) that APHIS provides an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 9/26/00

State: Arizona

Rptloc01/R4



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An Equal Opportunity Employer

SEP 21 2000

OR120018_BR_006623



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

August 24, 2000

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

Dear Mr. Brown:

Enclosed is notification 00-236-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-236-01n	Applicant #:	2000-536XRAB
Received:	August 23, 2000	Effective:	September 22, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date:

9/1/00

State:

MO

Rptloc01/R4



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SEP 7 2000

OR120018_BR_006624

TOTAL P.01

September 21, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 22, 2000.

Interstate movement and Release
Notification no. 00-236-01n (2000-536XRAB)
Regulated article - Wheat
Destinations - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
S. Soby, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-236-01n

OR120018_BR_006625

Confirmation Report-Memory Send

Time : Sep-21-00 01:38pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 420
Date : Sep-21 01:37pm
To : 916367377085
Document Pages : 01
Start time : Sep-21 01:38pm
End time : Sep-21 01:38pm
Pages sent : 01

Job number : 420

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

September 21, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 22, 2000.

Interstate movement and Release
Notification no. 00-236-01n (2000-536XRAB)
Regulated article - Wheat
Destinations - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
S. Soby, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA



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OR120018_BR_006626

2000 Wheat Field Trial Report
USDA # 00-236-01n Monsanto # 2000-536XRAB

Biotech Field Compliance Team
October 17, 2001
Monsanto Company

Location
Site 1

County
Yuma

State
AZ

Site 1

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-236-01n Monsanto # 2000-536XRAB

Biotech Field Compliance Team
October 17, 2001
Monsanto Company

Location
Site 1

County
Yuma

State
AZ

Site 1

Planting Date: October 16, 2000

Harvest Date: May 15, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT13, lines TA_S0317, TA_S0635, TA_S1081, TA_S2520, TA_S5450; PV-TXGT17, lines TA_S9240, TA_S9719; PV-TXGT23, lines TA_S7535, TA_S7890, TA_S9512, TA_S10430

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]
CBI

Disposition of the Harvested Material: [CBI deleted]

8/31/00 1:53 pm

Notification Tracking Sheet

=====
Bp number: 00-243-05n
=====

App number: 2000-580XRAB
Received: 8/30/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 9/29/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 9/28/00
End movement: 9/28/01
Begin release: 9/28/00
End release: 9/28/01
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|-----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [8/31/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>///</i>]* | [9/5/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>K2nd</i>] | [9/6/00]* |
| 4. <input type="checkbox"/> State response | | |

- | | O/d | Loc | Site | Reg | | |
|------------|--------|-----|------|------|---|-----|
| Interstate | *Dest* | KS | * | *SCR | * | [] |
| Interstate | *Dest* | WA | * | *WR | * | [] |
| Interstate | *Orig* | KS | * | *SCR | * | [] |
| Interstate | *Orig* | WA | * | *WR | * | [] |
| Release | * | *WA | * | 1*WR | * | [] |
-
- | | | |
|--|-----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [9/5/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>K2nd</i>] | [9/29/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>K2nd</i>] | [10/2/00] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2000-580XRAB

August 29, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-243-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-580XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 28, 2000 - September 28, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-580XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-580XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/5 -- [

(b)(4)

CBI

(b)(4)

Gene: CTP7-CP4 -- [

(b)(4)

CBI

(b)(4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [

(b)(4)

CBI

(b)(4)

CONFIDENTIAL

Monsanto Reference ID

2000-580XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

* [REDACTED] (b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,

] - CBI

WA

* [REDACTED] (b)(4) Walla Walla County/Province, WA, (b)(4) USA

CONTACT:

(b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

* [REDACTED] (b)(4) Adams County/Province, WA, (b)(4)

CONTACT:

(b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-580XRAB

Ship To:

KS

*[(b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,

] - CBI

WA

*[(b)(4), (b)(6), (b)(7)(C) Walla Walla County/Province, WA, (b)(4), (b)(6), (b)(7)(C) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

*[(b)(4) Adams County/Province, WA, (b)(4)

CONTACT: (b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-580XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[(b) (4), (b) (6), (b) (7)(C) Walla Walla County/Province, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

Food • Health • Hope



CONFIDENTIAL

Monsanto Reference ID

2000-580XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

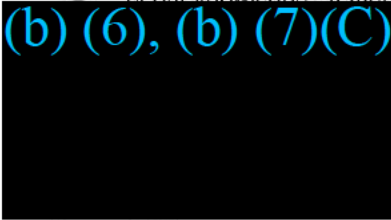
FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 29, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2000-580XRAB

August 29, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-243-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-580XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 28, 2000 - September 28, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

[CBI Deleted] -- *Adams County/Province, WA

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

[CBI Deleted] -- *Adams County/Province, WA

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 5 acres

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CBI-DELETED

Monsanto Reference ID

2000-580XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 29, 2000

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2000-580XRAB

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700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

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August 29, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-243-05n

1. USDA Reference Number

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FAX

636/737-7085

E-Mail

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Monsanto Company

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St. Louis

MO

63198

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Interstate Movement and Release

September 28, 2000 - September 28, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

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designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

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CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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GENE OF INTEREST

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CBI

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

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ORIGIN:

KS, WA

DESTINATION:

KS, WA

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

[CBI Deleted] -- *Adams County/Province, WA

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

[CBI Deleted] -- *Adams County/Province, WA

CBI-DELETED

Monsanto Reference ID

2000-580XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

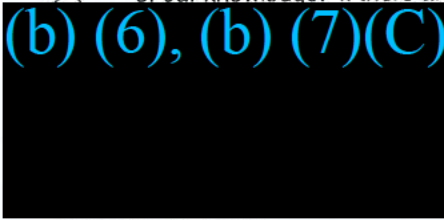
Monsanto Reference ID
2000-580XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
August 29, 2000

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 31, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-243-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-243-05n	Applicant #:	2000-580XRAB
Received:	August 30, 2000	Effective:	September 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006655

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

August 31, 2000

Dear Mr. Wessels:

Enclosed is notification 00-243-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-243-05n	Applicant #:	2000-580XRAB
Received:	August 30, 2000	Effective:	September 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006656



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

August 31, 2000

Dear Mr. Wessels:

Enclosed is notification 00-243-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-243-05n	Applicant #:	2000-580XRAB
Received:	August 30, 2000	Effective:	September 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C) /*for*

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Thomas L. Wessels*

Signature: *(b) (6), (b) (7)(C)*

Date: *9/7/00*

State: *WA*

Rptloc01/R4



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An Equal Opportunity Employer

SEP 7 2000

OR120018_BR_006657

September 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 29, 2000.

Interstate movement and Release
Notification no. 00-243-05n (2000-580XRAB)
Regulated article - Wheat
Destinations - Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-243-05n

OR120018_BR_006658

Confirmation Report-Memory Send

Time : Sep-29-00 04:35pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 579
Date : Sep-29 04:33pm
To : 916367377085
Document Pages : 01
Start time : Sep-29 04:34pm
End time : Sep-29 04:34pm
Pages sent : 01
Job number : 579

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

September 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 29, 2000.

Interstate movement and Release
Notification no. 00-243-05a (2000-580)RAB)
Regulated article - Wheat
Destinations - Kansas, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stroaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



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An Equal Opportunity Employer

OR120018_BR_006659

2000 Wheat Field Trial Report
USDA # 00-243-05n Monsanto # 2000-580XRAB

Biotech Field Compliance Team
October 17, 2001
Monsanto Company

Location
Site # 1

County
Walla Walla

State
WA

Site 1

Planting Date: October 9, 2000

Destruct Date: May 29, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Additional comments: [CBI deleted]

2000 Wheat Field Trial Report
USDA # 00-243-05n Monsanto # 2000-580XRAB

Biotech Field Compliance Team
October 17, 2001
Monsanto Company

Location
Site # 1

County
Walla Walla

State
WA

Site 1

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

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Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

9/19/00 1:01 pm

Notification Tracking Sheet

Bp number: 00-262-05n

App number: 2000-613XRAB
 Received: 9/18/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 10/18/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person:
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C)
 Begin movement: 10/14/00
 End movement: 10/14/01
 Begin release: 10/14/00
 End release: 10/14/01
 Acre: 6.00
 CBI status: CBI
 Fax: 636-737-7085

- | | Initial | Date |
|--|---------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ayd] | [9/20/2000] |
| 2. <input type="checkbox"/> Review by biotechnologist | [it]* | [9/20/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [KLD] | [9/21/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*AZ	*	*WR *
Interstate	*Dest*CA	*	*WR *
Interstate	*Dest*ID	*	*WR *
Interstate	*Orig*AZ	*	*WR *
Interstate	*Orig*CA	*	*WR *
Interstate	*Orig*ID	*	*WR *
Release	* *AZ	*	1*WR *
Release	* *CA	*	1*WR *
Release	* *ID	*	1*WR *

- | | | |
|--|---------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ayd] | [9/20/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KLD] | [10/10/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLD] | [10/10/00] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2000-613XRAB

September 14, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-262-05a

1. USDA Reference Number

2. Applicant Reference Number 2000-613XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

October 14, 2000 - October 14, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2000-613XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/5 -- [(b) (4)]
(b) (4)

CBI

Gene: CTP7-CP4 -- [(b) (4)]
(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [(b) (4)]
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [(b) (4)]
(b) (4)

CBI

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Monsanto Reference ID

2000-613XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 2000 pounds of wheat seed to and from each location.

ORIGIN:
AZ, CA, ID

DESTINATION:
AZ, CA, ID

Ship From:

AZ

(b) (4) Maricopa County/Province, AZ (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ,
(b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CA

*[(b) (4) Kings County/Province, CA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

ID

* (b) (4) Bingham County/Province, ID (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

Ship To:

AZ

*[(b) (4) Maricopa County/Province, AZ (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) , AZ,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CA

*[(b) (4) Kings County/Province, CA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

ID

*[(b) (4) Bingham County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1), CA (1), ID (1)

AZ

(b) (4), (b) (6), (b) (7)(C)

Pinal County/Province, AZ, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

AZ,

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Comments:

(b) (4), (b) (6), (b) (7)(C)

] - CBI

CA

(b) (4)

Kings County/Province, CA, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

AZ,

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

ID

(b) (4)

Bingham County/Province, ID, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

AZ,

(b) (4), (b) (6), (b) (7)(C)

USA

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

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CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

September 14, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

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IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

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CBI-DELETED

Monsanto Reference ID

2000-613XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

September 14, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-262-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-613XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

October 14, 2000 - October 14, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-613XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-613XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-613XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 2000 pounds of wheat seed to and from each location.

ORIGIN:

AZ, CA, ID

DESTINATION:

AZ, CA, ID

Ship From:

AZ

[CBI Deleted] -- *Maricopa County/Province, AZ, USA

CA

[CBI Deleted] -- *Kings County/Province, CA, USA

ID

[CBI Deleted] -- *Bingham County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-613XRAB

Ship To:

AZ

[CBI Deleted] -- *Maricopa County/Province, AZ, USA

CA

[CBI Deleted] -- *Kings County/Province, CA, USA

ID

[CBI Deleted] -- *Bingham County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-613XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1), CA (1), ID (1)

AZ

[CBI Deleted] -- Pinal County/Province, AZ, USA, 2 acres

CA

[CBI Deleted] -- Kings County/Province, CA, USA, 2 acres

ID

[CBI Deleted] -- Bingham County/Province, ID, USA, 2 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2000-613XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

September 14, 2000

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2000-613XRAB

September 14, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-262-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-613XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

October 14, 2000 - October 14, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

CBI

(b) (4)

Gene: CTP7-CP4 --

(b) (4)

CBI

(b) (4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 2000 pounds of wheat seed to and from each location.

ORIGIN:

AZ, CA, ID

DESTINATION:

AZ, CA, ID

Ship From:

AZ

(b) (4)

Maricopa County/Province, AZ (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

AZ,

] - CBI

CA

(b) (4)

Kings County/Province, CA (b) (4) USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

CA (b) (4), (b) (6), (b) (7)(C)

USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

ID

(b) (4)

Bingham County/Province, ID, (b) (4) USA

CONTACT:

USA (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ID

(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

Ship To:

AZ

*[(b) (4) Maricopa County/Province, AZ (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CA

*[(b) (4) Kings County/Province, CA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

ID

*[(b) (4) Bingham County/Province, ID (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) D (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1), CA (1), ID (1)

AZ

[(b) (4), (b) (6), (b) (7)(C) Pinal County/Province, AZ, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

Comments: Seed will be moved to release site on planting date.] - CBI

CA

[(b) (4) Kings County/Province, CA, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

ID

[(b) (4) Bingham County/Province, ID, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

Food • Health • Hope



CONFIDENTIAL

Monsanto Reference ID

2000-613XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

September 14, 2000

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2000-613XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

September 14, 2000

00-262-051

1. USDA Reference Number

2. Applicant Reference Number 2000-613XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

October 14, 2000 - October 14, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-613XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID
2000-613XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-613XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 2000 pounds of wheat seed to and from each location.

ORIGIN:

AZ, CA, ID

DESTINATION:

AZ, CA, ID

Ship From:

AZ

[CBI Deleted] -- *Maricopa County/Province, AZ, USA

CA

[CBI Deleted] -- *Kings County/Province, CA, USA

ID

[CBI Deleted] -- *Bingham County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-613XRAB

Ship To:

AZ

[CBI Deleted] -- *Maricopa County/Province, AZ, USA

CA

[CBI Deleted] -- *Kings County/Province, CA, USA

ID

[CBI Deleted] -- *Bingham County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID
2000-613XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1), CA (1), ID (1)

AZ

[CBI Deleted] -- Pinal County/Province, AZ, USA, 2 acres

CA

[CBI Deleted] -- Kings County/Province, CA, USA, 2 acres

ID

[CBI Deleted] -- Bingham County/Province, ID, USA, 2 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID
2000-613XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

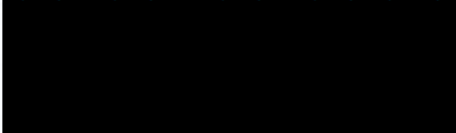
FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
September 14, 2000

file copy

Dr. Scott Sobey, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 19, 2000

Dear Dr. Sobey:

Enclosed is notification 00-262-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-262-05n	Applicant #:	2000-613XRAB
Received:	September 18, 2000	Effective:	October 18, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA ID		
Release destination:	AZ CA ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006703

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 19, 2000

Dear Ms. Hass:

Enclosed is notification 00-262-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-262-05n	Applicant #:	2000-613XRAB
Received:	September 18, 2000	Effective:	October 18, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA ID		
Release destination:	AZ CA ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006704

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

September 19, 2000

Dear Dr. Vega:

Enclosed is notification 00-262-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-262-05n	Applicant #:	2000-613XRAB
Received:	September 18, 2000	Effective:	October 18, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA ID		
Release destination:	AZ CA ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006705



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Scott Sobey, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 19, 2000

Dear Dr. Sobey:

Enclosed is notification 00-262-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-262-05n	Applicant #:	2000-613XRAB
Received:	September 18, 2000	Effective:	October 18, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA ID		
Release destination:	AZ CA ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravatta

Signature

(b) (6), (b) (7)(C)

Date:

9/25/00

State: Arizona

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

SEP 25 2000

OR120018_BR_006706

TOTAL P.02



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 19, 2000

Dear Ms. Hass:

Enclosed is notification 00-262-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ap number	00-262-05n	Applicant #:	2000-613XRAB
Received:	September 18, 2000	Effective:	October 18, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA ID		
Release destination:	AZ CA ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

for
E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination provided, the applicable requirements of CFR 301.89 are met.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbara J. Hass (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: October 2, 2000

California

State:

Rptloc01/R4

OCT 3 2000





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

RECEIVED

SEP 25 2000

PLANT INDUSTRIES

September 19, 2000

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

Dear Dr. Vega:

Enclosed is notification 00-262-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	00-262-05n	Applicant #:	2000-613XRAB
Received:	September 18, 2000	Effective:	October 18, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA ID		
Release destination:	AZ CA ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature:

(b) (6), (b) (7)(C)

Date:

Sept. 25, 2000

State:

IDAHO

Rptloc01/R4

SEP 26 2000



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006708

October 10, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 18, 2000.

Interstate movement and Release
Notification no. 00-262-05n (2000-613XRAB)
Regulated article - Wheat
Destinations - Arizona, California, Idaho

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of California concurs with APHIS determination; provided, the applicable requirements of CFR 301.89 are met.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

S. Soby, Arizona Dept. of Agric., Phoenix, AZ
B. Hass, California Dept. of Food and Agric., Sacramento, CA
R. Vega, Idaho Dept. of Agric., Boise, ID
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-262-05n

OR120018_BR_006709

Confirmation Report-Memory Send

Time : Oct-10-00 03:58pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 711
Date : Oct-10 03:57pm
To : 916367377085
Document Pages : 01
Start time : Oct-10 03:57pm
End time : Oct-10 03:58pm
Pages sent : 01

Job number : 711

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

October 10, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 18, 2000.

Interstate movement and Release
Notification no. 00-262-05n (2000-613XRAB)
Regulated article - Wheat
Destinations - Arizona, California, Idaho

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of California concurs with APHIS determination; provided, the applicable requirements of CFR 301.89 are met.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
S. Soby, Arizona Dept. of Agric., Phoenix, AZ
B. Hass, California Dept. of Food and Agric., Sacramento, CA
R. Vega, Idaho Dept. of Agric., Boise, ID
R. Stokas, PPQ, WR, Sacramento, CA



APHIS - Protecting America's Agriculture

An Equal Opportunity Employer

OR120018_BR_006710

2000 Wheat Field Trial Report
USDA # 00-262-05n Monsanto # 2000-613XRAB

December 19, 2001

Biotech Field Compliance Team
Monsanto Company

Location

Site 1

Site 2

Site 3

County

Pinal

Kings

Bingham

State

AZ (NOT PLANTED)

CA

ID (NOT PLANTED)

Site 1

Planting Date: December 6, 2000

Destruct Date: March 21, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT10 line 33391

Purpose of Trial: [CBI deleted]

[CBI deleted]

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-262-05n Monsanto # 2000-613XRAB

December 19, 2001

Biotech Field Compliance Team
Monsanto Company

Location

Site 1
Site 2
Site 3

County

Pinal
Kings
Bingham

State

AZ (NOT PLANTED)
CA
ID (NOT PLANTED)

Site 2

(b) (4)

=====

Bp number: 00-297-02n

=====

App number: 2000-661XRAB Begin movement: 11/19/00
 Received: 10/23/00 End movement: 11/19/01
 Institution: Monsanto Begin release: 11/19/00
 Recipient: Wheat End release: 11/19/01
 Status: Pending Acre: 3.00
 Effective date: 11/22/00 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

- | | Initial | Date |
|--|-----------------|----------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [10/23/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>ANK</i>]* | [10/24/2000] |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLD</i>] | [10/25/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg			
Interstate	*Dest*	HI	*	*WR	*	[]
Interstate	*Dest*	MO	*	*SCR	*	[]
Interstate	*Orig*	HI	*	*WR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Release	*	*HI	*	1*WR	*	[]

- | | | |
|--|----------------|----------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [10/24/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLD</i>] | [12/4/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLD</i>] | [12/4/00] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2000-661XRAB

October 20, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-297-02n

1. USDA Reference Number

2. Applicant Reference Number 2000-661XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

November 19, 2000 - November 19, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S0317, TA S0635, TA S1081, TA S2520, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- (b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S7535, TA S7890, TA S 9512

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 10,000 kg of wheat seed and leaf tissues to and from each location.

ORIGIN:

HI, MO

DESTINATION:

HI, MO

Ship From:

HI

*[(b) (4)] Honolulu
County/Province, HI (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO (b) (4)
U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

Ship To:

HI

*[(b) (4)] Honolulu
County/Province, HI, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

(b) (4) Honolulu
County/Province, HI, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

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FAX (636) 737-7085

<http://www.monsanto.com>

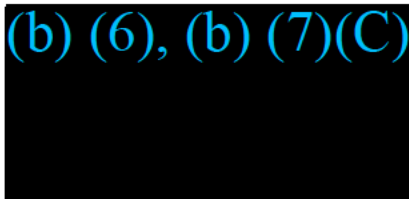
Monsanto Reference ID

2000-661XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

October 20, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2000-661XRAB

October 20, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-297-02n

1. USDA Reference Number

2. Applicant Reference Number 2000-661XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

November 19, 2000 - November 19, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S0317, TA S0635, TA S1081, TA S2520, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S7535, TA S7890, TA S 9512

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 10,000 kg of wheat seed and leaf tissues to and from each location.

ORIGIN:

HI, MO

DESTINATION:

HI, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, USA, 3 acres

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CBI-DELETED

Monsanto Reference ID

2000-661XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

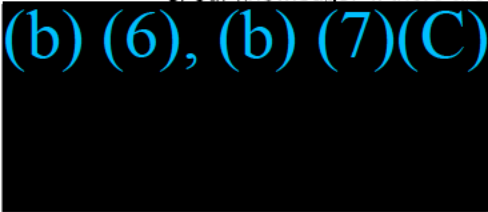
FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

October 20, 2000

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2000-661XRAB

Permit Unit

October 20, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-297-02n

1. USDA Reference Number

2. Applicant Reference Number 2000-661XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

November 19, 2000 - November 19, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S0317, TA S0635, TA S1081, TA S2520, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3'

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMB2/15-1

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S7535, TA S7890, TA S 9512

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-661XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 10,000 kg of wheat seed and leaf tissues to and from each location.

ORIGIN:
HI, MO

DESTINATION:
HI, MO

Ship From:

HI

* [REDACTED] (b) (4) Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT:

[REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT:

[REDACTED] (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

HI

* [REDACTED] (b) (4) Honolulu
County/Province, HI, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

CONTACT: [REDACTED]

(b) (4), (b) (6), (b) (7)(C)
[REDACTED] HI, [REDACTED] U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[REDACTED]
U.S.A.

(b) (4)

St. Louis County/Province, MO, (b) (4)

CONTACT: [REDACTED]

(b) (4), (b) (6), (b) (7)(C)
[REDACTED] U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-661XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[(b) (4) Honolulu
County/Province, HI, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

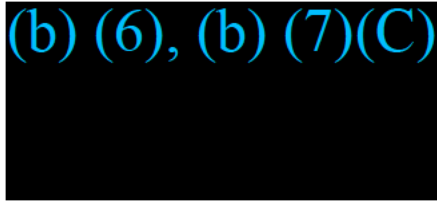
Monsanto Reference ID

2000-661XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

October 20, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2000-661XRAB

October 20, 2000

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

00-297-02n

1. **USDA Reference Number**
2. **Applicant Reference Number** 2000-661XRAB
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)

@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

November 19, 2000 - November 19, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S0317, TA S0635, TA S1081, TA S2520, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

designation of transformed line: TA S7535, TA S7890, TA S 9512

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 10,000 kg of wheat seed and leaf tissues to and from each location.

ORIGIN:

HI, MO

DESTINATION:

HI, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-661XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, USA, 3 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2000-661XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

October 20, 2000

• file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

October 23, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-297-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-297-02n	Applicant #:	2000-661XRAB
Received:	October 23, 2000	Effective:	November 22, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006754

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

October 23, 2000

Dear Mr. Brown:

Enclosed is notification 00-297-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-297-02n	Applicant #:	2000-661XRAB
Received:	October 23, 2000	Effective:	November 22, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006755

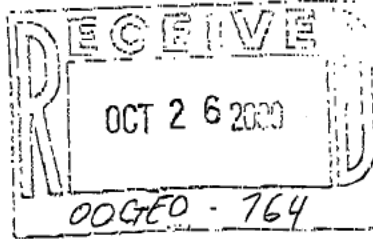


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



October 23, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-297-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-297-02n
Received: October 23, 2000
Institution: Monsanto
Interstate destination: HI MO
Release destination: HI

Applicant #: 2000-661XRAB
Effective: November 22, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Please notify Ms. Carol Okada,
Hawaii Dept. of Agriculture, 701 Ilalo St. Honolulu, HI 96813.
State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 1 December 2000

State: Hawaii

Rptloc01/R4



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DEC 1

OR120018_BR_006756



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

October 23, 2000

Dear Mr. Brown:

Enclosed is notification 00-297-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-297-02n	Applicant #:	2000-661XRAB
Received:	October 23, 2000	Effective:	November 22, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Ms. J. E. D.

Signature: (b) (6), (b) (7)(C)

Date: 11/6/00

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

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NOV 7 2000

OR120018_BR_006757

December 4, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after December 4, 2000.

Interstate movement and Release
Notification no. 00-297-02n (2000-661XRAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.
 - b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

OR120018_BR_006758

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
R. Elliston, PPQ, SCR, Fort Collins, CO
File number 00-297-02n

Confirmation Report-Memory Send

Time : Dec-04-00 04:29pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 329
Date : Dec-04 04:28pm
To : 916367377085
Document Pages : 02
Start time : Dec-04 04:28pm
End time : Dec-04 04:29pm
Pages sent : 02

Job number : 329

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

December 4, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after December 4, 2000.

Interstate movement and Release
Notification no. 00-297-02n (2000-661XRAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.
 - b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.



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OR120018_BR_006760

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January 29, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker:

The responsible researcher at Hawaii Agriculture Research Center has changed for the following wheat notifications.

USDA #	Monsanto #	Change
00-195-04n	2000-518XRAB	(b) (6), (b) (7)(C), (b) (4)
00-195-05n	2000-519XRAB	
00-195-06n	2000-520XRAB	
00-199-01n	2000-521XRAB	
00-199-02n	2000-522XRAB	
00-297-02n	2000-661XRAB	

To (b) (6), (b) (7)(C) phone 808/486-5020 fax. If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

OR120018_BR_006761

2000 Wheat Field Trial Report
USDA # 00-297-02n Monsanto # 2000-661XRAB

Biotech Field Compliance Team
October 17, 2001
Monsanto Company

Location
Site 1

County
Honolulu

State
HI

Site 1

(b)(4)

2000 Wheat Field Trial Report
USDA # 00-297-02n Monsanto # 2000-661XRAB

Biotech Field Compliance Team
October 17, 2001
Monsanto Company

Location
Site 1

County
Honolulu

State
HI

Site 1

Planting Date: December 7, 2000

Harvest Date: March 26, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT13, lines TA_ S0317, TA_ S0635, TA_ S1081, TA_ S5450;
PV-TXGT17, line TA_ S9240; PV-TXGT23, lines TA_ S7535, TA_ S7890, TA_ S 9512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteers: [CBI deleted]

10/25/00 10:57 am

Notification Tracking Sheet

=====

Bp number: 00-299-01n

=====

App number: 2000-664XRAB

Received: 10/25/00

Institution: Monsanto

Recipient: Wheat

Status: Pending

Effective date: 11/24/00

Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Begin movement: 11/23/00

End movement: 11/23/01

Begin release: 11/23/00

End release: 11/23/01

Acre: 5.00

CBI status: CBI

(b) (6), (b) (7)(C)

Fax: 636-737-7085

Initial

Date

1. ☒ Assign Bp number and initial data entry

[ajd]

[10/25/2000]

2. ☒ Review by biotechnologist

[JMK]*

[10/26/2000]

3. ☒ Letter of notification to State Fed-ex

[KLD]

[10/26/01]*

4. ☐ State response

O/d Loc Site Reg

Interstate *Dest*CO * *WR *

[] []

Interstate *Dest*KS * *SCR *

[] []

Interstate *Orig*CO * *WR *

Interstate *Orig*KS * *SCR *

Release * *NE * 1*SCR *

[] []

5. ☒ Enter genes into database

[apt]

[10/26/2000]

6. ☒ Letter of acknowledgement/denial/withdraw

[KLD]

[12/12/00]*

7. ☒ Enter final data into database

[KLD]

[12/18/00]

8. ☐ If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify

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Monsanto Reference ID
2000-664XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

October 24, 2000

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

00-299-01n

1. **USDA Reference Number**
2. **Applicant Reference Number** 2000-664XRAB
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

November 23, 2000 - November 23, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-664XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-664XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

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Monsanto Reference ID

2000-664XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

CO, KS

DESTINATION:

CO, KS

Ship From:

CO

* [REDACTED] (b) (4) Arapaho County/Province, CO, (b) (4) USA

CONTACT:

[REDACTED] (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

* [REDACTED] (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT:

[REDACTED] (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

Ship To:

CO

* [REDACTED] (b) (4) Arapaho County/Province, CO, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-664XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-664XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

NE (1)

NE

[(b) (4), (b) (6), (b) (7)(C)] Perkins County/Province, NE, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID

2000-664XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000


FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

October 24, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

Monsanto Reference ID
2000-664XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

October 24, 2000

00-299-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-664XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

Phone (b) (6), (b) (7)(C)
FAX 636/737-7085
EMail (b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

November 23, 2000 - November 23, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-664XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-664XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-664XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

CO, KS

DESTINATION:

CO, KS

Ship From:

CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

Ship To:

CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

CBI-DELETED

Monsanto Reference ID

2000-664XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-664XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

NE (1)

NE

[CBI Deleted] -- Perkins County/Province, NE, USA, 5 acres

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CBI-DELETED

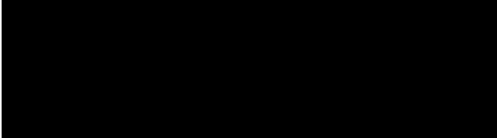
Monsanto Reference ID
2000-664XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
October 24, 2000

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Monsanto Reference ID

2000-664XRAB

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Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

October 24, 2000

00-299-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-664XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

November 23, 2000 - November 23, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2000-664XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-664XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-664XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:
CO, KS

DESTINATION:
CO, KS

Ship From:

CO

*[(b) (4) Arapaho County/Province, CO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

*[(b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

Ship To:

CO

*[(b) (4) Arapaho County/Province, CO (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2000-664XRAB

CONTACT (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

*[(b) (4)] Sedgwick County/Province, KS (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-664XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

NE (1)

NE

(b) (4), (b) (6), (b) (7)(C) Perkins County/Province, NE, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

Food • Health • Hope



CONFIDENTIAL

Monsanto Reference ID

2000-664XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

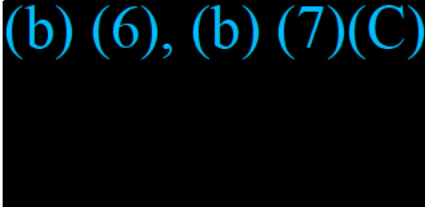
FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

October 24, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2000-664XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Permit Unit

October 24, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-299-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-664XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

November 23, 2000 - November 23, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-664XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

Not FOIA Deletions

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-664XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-664XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1200 pounds of wheat seed to and from each location.

ORIGIN:

CO, KS

DESTINATION:

CO, KS

Ship From:

CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

Ship To:

CO

[CBI Deleted] -- *Arapaho County/Province, CO, USA

CBI-DELETED

Monsanto Reference ID
2000-664XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID
2000-664XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

NE (1)

NE

[CBI Deleted] -- Perkins County/Province, NE, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

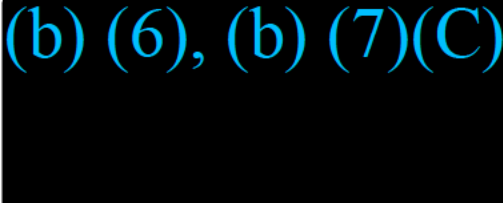
Monsanto Reference ID
2000-664XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
October 24, 2000

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

October 25, 2000

Dear Mr. Yergert:

Enclosed is notification 00-299-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-299-01n	Applicant #:	2000-664XRAB
Received:	October 25, 2000	Effective:	November 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS		
Release destination:	NE		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006801

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

October 25, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-299-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-299-01n	Applicant #:	2000-664XRAB
Received:	October 25, 2000	Effective:	November 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS		
Release destination:	NE		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006802

file copy

Mr. Stephen V. Johnson, State Entomologist
Bureau of Plant Industry
Nebraska Department of Agriculture
301 Centennial Mall South - 4th Floor
Lincoln, NE 68509-4756

October 25, 2000

Dear Mr. Johnson:

Enclosed is notification 00-299-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-299-01n	Applicant #:	2000-664XRAB
Received:	October 25, 2000	Effective:	November 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS		
Release destination:	NE		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006803



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Mitch Vergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

October 25, 2000

Dear Mr. Vergert:

Enclosed is notification 00-299-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number	00-299-01n	Applicant #:	2000-664XRAB
Received:	October 25, 2000	Effective:	November 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS		
Release destination:	NE		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Vergert

Signature: (b) (6), (b) (7)(C)

Date: November 1, 2000

State: Colorado

RptLoc01/R4



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An Equal Opportunity Employer

OR120018_BR_006804



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

NEBRASKA
BUREAU OF
PLANT INDUSTRY
RECEIVED

OCT 30 2000

Cash M.O.

Check October 25, 2000

Mr. Stephen V. Johnson, State Entomologist
Bureau of Plant Industry
Nebraska Department of Agriculture
301 Centennial Mall South - 4th Floor
Lincoln, NE 68509-4756

Dear Mr. Johnson:

Enclosed is notification 00-299-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-299-01n
Received: October 25, 2000
Institution: Monsanto
Interstate destination: CO KS
Release destination: NE

Applicant #: 2000-664XRAB
Effective: November 24, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen V. Johnson

Signature: (b) (6), (b) (7)(C)

Date: 12/12/00

State: Nebraska

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006805

December 12, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after December 12, 2000.

Interstate movement and Release
Notification no. 00-299-01n (2000-664XRAB)
Regulated article - Wheat
Destinations - Colorado, Kansas, Nebraska

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
T. Sim, Kansas State Board of Agric., Topeka, KS
S. Johnson, Nebraska Dept. of Agric., Lincoln, NE
R. Elliston, PPQ, SCR, Fort Collins, CO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-299-01n

OR120018_BR_006806

Confirmation Report-Memory Send

Time : Dec-12-00 07:08pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 413
Date : Dec-12 07:07pm
To : 916367377085
Document Pages : 01
Start time : Dec-12 07:07pm
End time : Dec-12 07:08pm
Pages sent : 01
Job number : 413

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

December 12, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after December 12, 2000.

Interstate movement and Release
Notification no. 00-299-01n (2000-664XPAB)
Regulated article - Wheat
Destinations - Colorado, Kansas, Nebraska

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
M. Vergert, Colorado Dept. of Agric., Lakewood, CO
T. Sam, Kansas State Board of Agric., Topeka, KS
S. Johnson, Nebraska Dept. of Agric., Lincoln, NE
R. Elliston, PPQ, SCR, Fort Collins, CO
R. Stoaks, PPQ, WR, Sacramento, CA



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OR120018_BR_006807

MONSANTO



June 4, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

USDA notification number 00-299-01n, Monsanto number 2000-664XRAB
for movement and release is canceled.

If you need further information, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

cc: R Stoaks, USDA APHIS, PPQ, Sacramento, CA
M. Yergert, CO Dept. of Agri, Lakewood, CO

OR120018_BR_006808

ajb
6/6/01

NO CBI

2000 Wheat Field Test Report
USDA #00-299-01n Monsanto #2000-664XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

Location

2147305416

County

Perkins County

State

NE

Not Planted

1/17/01 4:21 pm

Notification Tracking Sheet

=====
Bp number: 01-016-18n
=====

App number: 2001-60XRAB
Received: 1/16/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/15/01
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/08/01
End movement: 2/08/02
Begin release: 2/08/01
End release: 2/08/02
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [apd] | [1/17/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [AMK]* | [1/18/01]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLnO] | [1/23/01]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	HI	*	*WR *
Interstate	*Dest*	ID	*	*WR *
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Orig*	HI	*	*WR *
Interstate	*Orig*	ID	*	*WR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	MO	*	*SCR *
Release	*	ID	*	1*WR *

- | | | |
|--|----------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [apd] | [1/18/01] |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw | [KLnO] | [2/16/01]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLnO] | [2/26/01] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-60XRAB

January 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-60XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2001-60XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2001-60XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 3000 pound of wheat seed to and from each location

ORIGIN:
HI, ID, KS, MO

DESTINATION:
HI, ID, KS, MO

Ship From:

HI

*[(b) (4)] Honolulu
County/Province, HI (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)
] - CBI

ID

*[(b) (4), (b) (6), (b) (7)(C)] Bannock County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

*[(b) (4)] Twin Falls County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

KS

*[(b) (4)] Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4)
U.S.A.

CONFIDENTIAL

Monsanto Reference ID
2001-60XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) St. Louis, MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A.,
] - CBI

Ship To:

HI

*[(b) (4) Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
] - CBI

ID

*[(b) (4), (b) (6), (b) (7)(C) Bannock County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

*[(b) (4) Twin Falls County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A.,
] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-60XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1)

ID

(b) (4), (b) (6), (b) (7)(C) Bannock County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2001-60XRAB

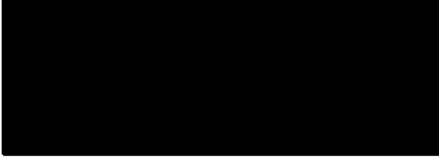
MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 09, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-60XRAB

January 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-60XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-60XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2001-60XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 3000 pound of wheat seed to and from each location

ORIGIN:

HI, ID, KS, MO

DESTINATION:

HI, ID, KS, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Bannock County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2001-60XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Bannock County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2001-60XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1)

ID

[CBI Deleted] -- Bannock County/Province, ID, USA, 5 acres

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CBI-DELETED

Monsanto Reference ID

2001-60XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 09, 2001

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CBI-DELETED

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Monsanto Reference ID

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Monsanto Company

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St. Louis

MO

63198

4. Duration of Introduction

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5. Recipient

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CBI-DELETED

Monsanto Reference ID

2001-60XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

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CBI

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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CBI

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-60XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 3000 pound of wheat seed to and from each location

ORIGIN:

HI, ID, KS, MO

DESTINATION:

HI, ID, KS, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Bannock County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2001-60XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Bannock County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2001-60XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1)

ID

[CBI Deleted] -- Bannock County/Province, ID, USA, 5 acres

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CBI-DELETED

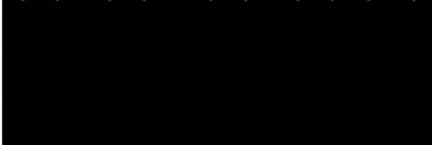
MONSANTO COMPANY
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CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2001-60XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 09, 2001

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-18n	Applicant #:	2001-60XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006833

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 17, 2001

Dear Dr. Vega:

Enclosed is notification 01-016-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-18n	Applicant #:	2001-60XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

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ISI

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

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STATE RESPONSE TO NOTIFICATION

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_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006834

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-18n	Applicant #:	2001-60XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

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Sincerely,

15/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006835

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-18n	Applicant #:	2001-60XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

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Sincerely,

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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006836

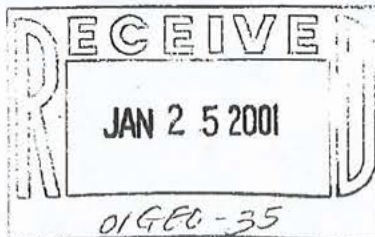


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-18n	Applicant #:	2001-60XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 15 February 2001

State: Hawaii

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Rivergale, MD 20737

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

RECEIVED

January 17, 2001

JAN 25 2001

PLANT INDUSTRIES

Dear Dr. Vega:

Enclosed is notification 01-016-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-18n	Applicant #:	2001-60XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION



State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature:

(b) (6), (b) (7)(C)

Date: Jan. 26, 2001

State: IDAHO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006838

JAN 26 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-016-18n Applicant #: 2001-60XRAB
Received: January 16, 2001 Effective: February 15, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI ID KS MO
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/2/01

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006839

3147510005 P.07/17

DEPT OF AGRICULTURE

FEB 5 2001

FEB-05-2001 12:41

February 16, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release
Notification no. 01-016-18n (2001-60XRAB)
Regulated article - Wheat
Destinations - Hawaii, Idaho, Kansas, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_006840

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI

R. Vega, Idaho Dept. of Agric., Boise, ID

T. Sim, Kansas State Board of Agric., Topeka, KS

M. Brown, Missouri Dept of Agric., Jefferson City, MO

R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-016-18n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK		916367377085	038/038	00:00:28

***** - - - *****



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release
Notification no. 01-037-12n (2001-339XRAB)
Regulated article - Wheat
Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, SCR, WR, Sacramento, CA



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006842

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-016-18n Monsanto #2001-60XRAB

DRAFT
September 26, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2147306740

County
Bannock County

State
ID

Bannock County/ID (2147306740)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, they are accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-016-18n Monsanto #2001-60XRAB**

**DRAFT
September 26, 2002**

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147306740	Bannock County	ID

Bannock County/ID (2147306740)

Planting Date: 04/30/2001

Destruct Date: 10/18/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 04/30/2001

Destruct Date: 10/18/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Planting Date: 04/30/2001

Destruct Date: 10/18/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 04/30/2001

Destruct Date: 10/18/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

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¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

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In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

1/17/01 4:21 pm

Notification Tracking Sheet

=====
Bp number: 01-016-19n
=====

App number: 2001-62XRAB
Received: 1/16/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/15/01
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/08/01
End movement: 2/08/02
Begin release: 2/08/01
End release: 2/08/02
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|--------------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apd</i>] | [1/17/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>Link</i>] * | [1/18/01] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>K&L</i>] | [1/23/01] * |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	HI	*	*WR *
Interstate	*Dest*	ID	*	*WR *
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Orig*	HI	*	*WR *
Interstate	*Orig*	ID	*	*WR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	MO	*	*SCR *
Release	*	ID	*	1*WR *

- | | | |
|--|--------------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apd</i>] | [1/18/01] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>K&L</i>] | [2/16/01] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>K&L</i>] | [2/24/01] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

Reason for tardiness - (KS) did not respond

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-62XRAB

January 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-19n

1. USDA Reference Number

2. Applicant Reference Number 2001-62XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

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Monsanto Reference ID
2001-62XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b)(4) CBI
(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4) CBI
(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2001-62XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:
HI, ID, KS, MO

DESTINATION:
HI, ID, KS, MO

Ship From:

HI

* [REDACTED] (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)
] - CBI

ID

* [REDACTED] (b)(4) Twin Falls County/Province, ID, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ID, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)
] - CBI

* [REDACTED] (b)(4) Twin Falls
County/Province, ID, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ID, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)
] - CBI

KS

* [REDACTED] (b)(4) Sedgwick County/Province, KS (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,
(b)(4), (b)(6), (b)(7)(C)
] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-62XRAB

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,
] - CBI

Ship To:

HI

*[(b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)
] - CBI

ID

*[(b)(4) Twin Falls County/Province, ID, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ID, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)
] - CBI

*[(b)(4) Twin Falls
County/Province, ID, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ID, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)
] - CBI

KS

*[(b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,
(b)(4), (b)(6), (b)(7)(C)
] - CBI

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)
] - CBI

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Monsanto Reference ID
2001-62XRAB

CONFIDENTIAL

Monsanto Reference ID
2001-62XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1)

ID

[(b)(4) Twin Falls County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ID, (b)(4), (b)(6), (b)(7)(C) USA (b)(4), (b)(6), (b)(7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-62XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 09, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-62XRAB

January 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-19n

1. USDA Reference Number

2. Applicant Reference Number 2001-62XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-62XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-62XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

HI, ID, KS, MO

DESTINATION:

HI, ID, KS, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-62XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-62XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1)

ID

[CBI Deleted] -- Twin Falls County/Province, ID, USA, 5 acres

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Monsanto Reference ID

2001-62XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 09, 2001

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January 09, 2001

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1. USDA Reference Number

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3. Applicant/Responsible Party

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Phone

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FAX

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E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-62XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-62XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

HI, ID, KS, MO

DESTINATION:

HI, ID, KS, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2001-62XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID

2001-62XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1)

ID

[CBI Deleted] -- Twin Falls County/Province, ID, USA, 5 acres

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<http://www.monsanto.com>

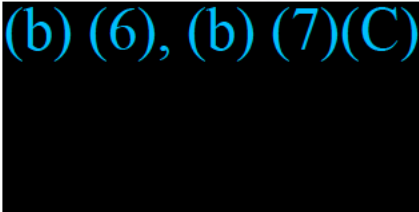
Monsanto Reference ID

2001-62XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 09, 2001

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-19n	Applicant #:	2001-62XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006878

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 17, 2001

Dear Dr. Vega:

Enclosed is notification 01-016-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-19n	Applicant #:	2001-62XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

1S)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006879

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-19n	Applicant #:	2001-62XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006880

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-19n	Applicant #:	2001-62XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006881

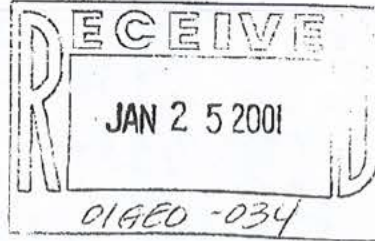


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-19n	Applicant #:	2001-62XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,
(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol I. Okada

Signature: (b) (6), (b) (7)(C)

Date: 15 February 2001

State: Hawaii

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 17, 2001

RECEIVED

JAN 25 2001

PLANT INDUSTRIES

Dear Dr. Vega:

Enclosed is notification 01-016-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-19n	Applicant #:	2001-62XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

(b) (6), (b) (7)(C)

Date: Jan. 26, 2001

State: IDAHO

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_006883

JAN 26 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	01-016-19n	Applicant #:	2001-62XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/2/01

State: MD

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 15 2001

OR120018_BR_006884

February 16, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release
Notification no. 01-016-19n (2001-62XRAB)
Regulated article - Wheat
Destinations - Hawaii, Idaho, Kansas, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_006885

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, SCR, Sacramento, CA
File number 01-016-19n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44 END=FEB-23 17:59

FILE NO.=497

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	*	916367377085	038/038	00:08:28

***** - - *****



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release
Notification no. 01-037-12n (2001-339XRAB)
Regulated article - Wheat
Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, SCR, WR, Sacramento, CA



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An Equal Opportunity Employer

OR120018_BR_006887

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-016-19n Monsanto #2001-62XRAB

September 26, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2147306759

County
Twin Falls County

State
ID

Twin Falls County/ID (2147306759)

(b)(4)

(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-016-19n Monsanto #2001-62XRAB**

September 26, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147306759	Twin Falls County	ID

Twin Falls County/ID (2147306759)

Planting Date: 04/11/2001

Harvest Date: 09/06/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 04/11/2001

Harvest Date: 09/06/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

1/17/01 4:21 pm

Notification Tracking Sheet

=====
Bp number: 01-016-20n
=====

App number: 2001-67XRAB
Received: 1/16/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/15/01
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/08/01
End movement: 2/08/02
Begin release: 2/08/01
End release: 2/08/02
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|-----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [apd] | [1/17/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [LMK] * | [1/18/01] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [K&D] | [1/23/01] * |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	HI	*	*WR *
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Dest*	WA	*	*WR *
Interstate	*Orig*	HI	*	*WR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	MO	*	*SCR *
Interstate	*Orig*	WA	*	*WR *
Release	*	WA	*	1*WR *

- | | | |
|--|---------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [apd] | [1/18/01] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [K&D] | [2/16/01] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [K&D] | [2/26/01] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

reason for tardiness: (KS) did not respond

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-67XRAB

January 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-20n

1. USDA Reference Number

2. Applicant Reference Number 2001-67XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2001-67XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b)(4)
(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)
(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2001-67XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, WA

DESTINATION:

HI, KS, MO, WA

Ship From:

HI

*[(b)(4)] Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)
] - CBI

KS

*[(b)(4)] Sedgwick County/Province, KS, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,
] - CBI

MO

*[(b)(4)] St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C) MO,
] - CBI

WA

*[(b)(4)] Whitman County/Province, WA, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)
] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-67XRAB

*[(b)(4)] Whittman
County/Province, WA, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)
] - CBI

Ship To:

HI

*[(b)(4)] Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)
] - CBI

KS

*[(b)(4)] Sedgwick County/Province, KS (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) , KS, (b)(4), (b)(6), (b)(7)(C) USA,
] - CBI

MO

*[(b)(4)] St. Louis County/Province, MO, (b)(4)
U.S.A

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) U.S.A, (b)(4), (b)(6), (b)(7)(C) MO,
] - CBI

WA

*[(b)(4)] Whitman County/Province, WA, USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)
] - CBI

*[(b)(4)] Whittman
County/Province, WA, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)
] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-67XRAB

CONFIDENTIAL

Monsanto Reference ID
2001-67XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[(b)(4) Whitman County/Province, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

MONSANTO

Food · Health · Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

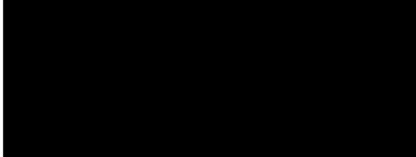
Monsanto Reference ID

2001-67XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 09, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

Food · Health · Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-67XRAB

January 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-20n

1. USDA Reference Number

2. Applicant Reference Number 2001-67XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-67XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2001-67XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, WA

DESTINATION:

HI, KS, MO, WA

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Whittman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2001-67XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Whittman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2001-67XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Whitman County/Province, WA, USA, 5 acres

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

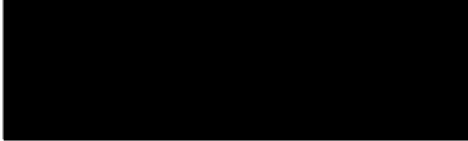
Monsanto Reference ID

2001-67XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 09, 2001

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-67XRAB

January 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-20n

1. **USDA Reference Number**

2. **Applicant Reference Number** 2001-67XRAB

3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. **Duration of Introduction**

Interstate Movement and Release

February 08, 2001 - February 08, 2002

5. **Recipient**

Wheat, Triticum aestivum

6. **Regulated Article**

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID
2001-67XRAB

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Constructs: PV-TXGT10

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CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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CBI

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CBI-DELETED

Monsanto Reference ID

2001-67XRAB

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HI, KS, MO, WA

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Monsanto Reference ID

2001-67XRAB

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[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

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[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Whittman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-67XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Whitman County/Province, WA, USA, 5 acres

MONSANTO

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CBI-DELETED

Monsanto Reference ID
2001-67XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
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(b) (6), (b) (7)(C)



Monsanto Company
January 09, 2001

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-20n	Applicant #:	2001-67XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

IS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006918

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-20n	Applicant #:	2001-67XRAB
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Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO WA		
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Sincerely,

/s/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006919

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Sincerely,

151

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006920

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 17, 2001

Dear Mr. Wessels:

Enclosed is notification 01-016-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-20n	Applicant #:	2001-67XRAB
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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

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_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006921

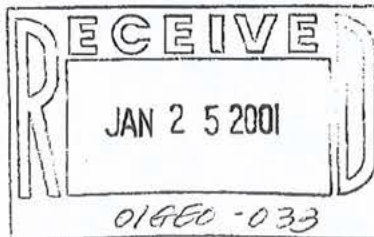


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



January 17, 2001

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Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: (b) (6), (b) (7)(C) Okada

Signature: (b) (6), (b) (7)(C)

Date: 15 February 2001

State: Hawaii

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006922

FEB 16 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

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Interstate destination:	HI KS MO WA		
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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/2/01

State: MO

Rptloc01/R4

FEB 15 2001



APHIS - Protecting American Agriculture

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OR120018_BR_006923



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

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STATE RESPONSE TO NOTIFICATION

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☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/1/01

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 2 2001

OR120018_BR_006924

February 16, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release
Notification no. 01-016-20n (2001-67XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(S)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS

OR120018_BR_006925

M. Brown, Missouri Dept of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, SCR, Sacramento, CA
File number 01-016-20n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK		916367377065	038/038	00:00:28



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release
Notification no. 01-037-12n (2001-339XRAB)
Regulated article - Wheat
Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, SCR, WR, Sacramento, CA



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An Equal Opportunity Employer

OR120018_BR_006927

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-016-20n Monsanto #2001-67XRAB

September 26, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2147306763

County
Whitman County

State
WA

Whitman County/WA (2147306763)

(b)(4)

(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-016-20n Monsanto #2001-67XRAB**

September 26, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147306763	Whitman County	WA

Whitman County/WA (2147306763)

Planting Date: 04/20/2001

Harvest Date: 08/29/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 04/20/2001

Harvest Date: 08/29/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

1/17/01 4:21 pm

Notification Tracking Sheet

=====
Bp number: 01-016-21n
=====

App number: 2001-70XRAB
Received: 1/16/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/15/01
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/09/01
End movement: 2/09/02
Begin release: 2/09/01
End release: 2/09/02
Acre: 25.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|---------|------------|
| 1. [✓] Assign Bp number and initial data entry | [epd] | [1/17/01] |
| 2. [✓] Review by biotechnologist | [mk]* | [1/18/01]* |
| 3. [✓] Letter of notification to State <i>Fed-ex</i> | [K&O] | [1/23/01]* |
| 4. [] State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*HI	*	*WR *
Interstate	*Dest*ID	*	*WR *
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*WA	*	*WR *
Interstate	*Orig*HI	*	*WR *
Interstate	*Orig*ID	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*WA	*	*WR *
Release	* *FL	*	3*SER *
Release	* *ID	*	1*WR *
Release	* *WA	*	1*WR *

- | | | |
|---|-------|------------|
| 5. [✓] Enter genes into database | [epd] | [1/18/01] |
| 6. [✓] Letter of <u>acknowledgement</u> /denial/withdraw | [K&O] | [2/27/01]* |
| 7. [✓] Enter final data into database | [K&O] | [2/27/01] |
| 8. [] If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

Reason for tardiness: (KS) did not respond

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-70XRAB

January 10, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-21n

1. USDA Reference Number

2. Applicant Reference Number 2001-70XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/ Variety Bobwhite

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Monsanto Reference ID
2001-70XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2001-70XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:
HI, ID, KS, MO, WA

DESTINATION:
HI, ID, KS, MO, WA

Ship From:

HI

*[(b)(4) Honolulu
County/Province, HI (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

ID

*[(b)(4) Latah County/Province, ID, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) ID, (b)(4), (b)(6), (b)(7)(C) USA,

] - CBI

KS

*[(b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-70XRAB

WA

*[(b) (4), (b) (6), (b) (7)(C)] Adams County/Province, WA, USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] ID, [(b) (4), (b) (6), (b) (7)(C)] USA,
[(b) (4), (b) (6), (b) (7)(C)]
]- CBI

Ship To:

HI

*[(b) (4)] (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: [(b) (4), (b) (6), (b) (7)(C)]
[(b) (4), (b) (6), (b) (7)(C)] HI, [(b) (4), (b) (6), (b) (7)(C)] U.S.A. [(b) (4), (b) (6), (b) (7)(C)]
]- CBI

ID

*[(b) (4)] Latah County/Province, ID (b)(4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] ID, [(b) (4), (b) (6), (b) (7)(C)] USA,
[(b) (4), (b) (6), (b) (7)(C)]
]- CBI

KS

*[(b) (4)] Sedgwick County/Province, KS (b)(4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] KS, [(b) (4), (b) (6), (b) (7)(C)] USA,
[(b) (4), (b) (6), (b) (7)(C)]
]- CBI

MO

*[(b) (4)] St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MO,
[(b) (4), (b) (6), (b) (7)(C)] U.S.A. [(b) (4), (b) (6), (b) (7)(C)]
]- CBI

WA

*[(b) (4), (b) (6), (b) (7)(C)] Adams County/Province, WA, USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] ID, [(b) (4), (b) (6), (b) (7)(C)] USA,
[(b) (4), (b) (6), (b) (7)(C)]
]- CBI

CONFIDENTIAL

Monsanto Reference ID

2001-70XRAB

CONFIDENTIAL

Monsanto Reference ID
2001-70XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

FL (3), ID (1), WA (1)

FL

[(b) (4), (b) (6), (b) (7)(C) St. Johns County/Province, FL, U.S.A., 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4), (b) (6), (b) (7)(C) St. Johns County/Province, FL, U.S.A., 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4), (b) (6), (b) (7)(C) St. Johns County/Province, FL, U.S.A., 5 acres.

RESPONSIBLE PERSON/RESEARCHER: D (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

ID

[(b)(4) Latah County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

(b) (4), (b) (6), (b) (7)(C) Adams County/Province, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-70XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 10, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-70XRAB

January 10, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-21n

1. USDA Reference Number

2. Applicant Reference Number 2001-70XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/ Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-70XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-70XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

HI, ID, KS, MO, WA

DESTINATION:

HI, ID, KS, MO, WA

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-70XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-70XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

FL (3), ID (1), WA (1)

FL

[CBI Deleted] -- St. Johns County/Province, FL, U.S.A., 5 acres

[CBI Deleted] -- St. Johns County/Province, FL, U.S.A., 5 acres

[CBI Deleted] -- St. Johns County/Province, FL, U.S.A., 5 acres

ID

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

WA

[CBI Deleted] -- Adams County/Province, WA, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2001-70XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 10, 2001

MONSANTO

Food · Health · Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID

2001-70XRAB

January 10, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-21n

1. USDA Reference Number

2. Applicant Reference Number 2001-70XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

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E Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

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Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/ Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-70XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

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CBI

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CBI-DELETED

Monsanto Reference ID

2001-70XRAB

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HI, ID, KS, MO, WA

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KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-70XRAB

Ship To:

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[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-70XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

FL (3), ID (1), WA (1)

FL

[CBI Deleted] -- St. Johns County/Province, FL, U.S.A., 5 acres

[CBI Deleted] -- St. Johns County/Province, FL, U.S.A., 5 acres

[CBI Deleted] -- St. Johns County/Province, FL, U.S.A., 5 acres

ID

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

WA

[CBI Deleted] -- Adams County/Province, WA, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-70XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 10, 2001

file copy

Ms. Connie Riherd, Assistant Director
Division of Plant Industry
Florida Dept of Agriculture and Consumer Services
1911 SW 34th Street
Gainesville, FL 32608

January 17, 2001

Dear Ms. Riherd:

Enclosed is notification 01-016-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-21n	Applicant #:	2001-70XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO WA		
Release destination:	FL ID WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: . , PPQ, S. Wood, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006958

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-21n	Applicant #:	2001-70XRAB
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Sincerely,

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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006959

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

January 17, 2001

Dear Dr. Vega:

Enclosed is notification 01-016-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-21n	Applicant #:	2001-70XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
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Sincerely,

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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006960

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-21n	Applicant #:	2001-70XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO WA		
Release destination:	FL ID WA		

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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006961

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-21n	Applicant #:	2001-70XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO WA		
Release destination:	FL ID WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006962

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 17, 2001

Dear Mr. Wessels:

Enclosed is notification 01-016-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-21n	Applicant #:	2001-70XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI ID KS MO WA		
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Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

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Sincerely,

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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006963



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

REC'D ADM.
JAN 24 2001

Ms. Connie Riherd, Assistant Director
Division of Plant Industry
Florida Dept of Agriculture and Consumer Services
1911 SW 34th Street
Gainesville, FL 32608

January 17, 2001

Dear Ms. Riherd:

Enclosed is notification 01-016-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-21n	Applicant #:	2001-70XRAB
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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: , PPQ, S. Wood, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Connie Riherd

Signature:

(b) (6), (b) (7)(C)

Date: 1-24-01

State:

FL

Rptloc01/R4



JAN 24 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 15 February 2001

State: Hawaii

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

RECEIVED
JAN 24 2001
PLANT INDUSTRIES

January 17, 2001

Dear Dr. Vega:

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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State: _____

Signature: _____

Date: Jan. 24, 2001

State: IDAHO

Rptloc01/R4.





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

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Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 01/31/01

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_006967

FEB 5 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 17, 2001

Dear Mr. Wessels:

Enclosed is notification 01-016-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-016-21n Applicant #: 2001-70XRAB
Received: January 16, 2001 Effective: February 15, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI ID KS MO WA
Release destination: FL ID WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 02/01/01

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 2 2001

OR120018_BR_006968

February 16, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 16, 2001.

Interstate movement and Release

Notification no. 01-016-21n (2001-70XRAB)

Regulated article - Wheat

Destinations - Florida, Hawaii, Idaho, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_006969

cc:

C. Riherd, Florida Dept. of Agric. and Consumer Services, Gainesville, FL
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-016-21n

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44

END=FEB-23 17:59

FILE NO.=497

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	S	916367377085	038/038	00:08:28

***** - - - - -



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release
Notification no. 01-017-12n (2001-339XRAB)
Regulated article - Wheat
Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, SCR, WR, Sacramento, CA



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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

February 5, 2001

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Per my conversation with Mary Jackson on February 5, 2001. I am withdrawing Monsanto wheat application 2001-70XRAB. We supplied an incorrect site location.

01-016-21N

I am submitting Monsanto wheat 2000-338XRAB to take its place, please expedite this notification.

If you have any additional questions, my telephone number is (b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) I apologize for any inconvenience.

Sincerely,

(b) (6), (b) (7)(C)

epd

OR120018_BR_006972

NO CBI

2001 Wheat Field Test Report
USDA #01-016-21n Monsanto #2001-70XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
-2058147896	St. Johns County	FL	Not Planted
-2058147896	St. Johns County	FL	Not Planted
-2058147896	St. Johns County	FL	Not Planted
2147303312	Latah County	ID	Not Planted
2147306778	Adams County	WA	Not Planted

1/17/01 4:21 pm

Notification Tracking Sheet

=====
Bp number: 01-016-22n
=====

App number: 2001-71XRAB
Received: 1/16/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/15/01
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/09/01
End movement: 2/09/02
Begin release: 2/09/01
End release: 2/09/02
Acre: 5.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|-----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [apd] | [1/17/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [LMK] * | [1/18/01] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLRD] | [1/23/01] * |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*HI	*	*WR *
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*OR	*	*WR *
Interstate	*Orig*HI	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*OR	*	*WR *
Release	*OR	*	1*WR *

- | | | |
|--|----------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [apd] | [1/18/01] |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw | [KLRD] | [2/21/01] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLRD] | [2/28/01] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

Reason for tardiness: (KS) did not respond

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CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-71XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

January 10, 2001

01-016-22n

1. USDA Reference Number

2. Applicant Reference Number 2001-71XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2001-71XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2001-71XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, OR

DESTINATION:

HI, KS, MO, OR

Ship From:

HI

*[(b)(4) (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI (b)(4), (b)(6), (b)(7)(C) U.S.A. (b)(4), (b)(6), (b)(7)(C)
] - CBI

KS

*[M (b)(4) Sedgwick County/Province, KS (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,
(b)(4), (b)(6), (b)(7)(C)
] - CBI

MO

*[(b)(4) St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A. (b)(4), (b)(6), (b)(7)(C)
] - CBI

OR

*[(b)(4) Umatilla County/Province, OR (b)(4)
USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) OR,
(b)(4), (b)(6), (b)(7)(C) USA (b)(4), (b)(6), (b)(7)(C)
] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-71XRAB

Ship To:

HI

*[REDACTED] (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: [REDACTED] (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

KS

*[REDACTED] (b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONTACT: [REDACTED] (b)(4), (b)(6), (b)(7)(C) KS, (b)(4), (b)(6), (b)(7)(C) USA,
(b)(4), (b)(6), (b)(7)(C)

] - CBI

MO

*[REDACTED] (b)(4) St. Louis County/Province, MO (b)(4)
U.S.A

CONTACT: [REDACTED] (b)(4), (b)(6), (b)(7)(C) MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

OR

*[REDACTED] (b)(4) Umatilla County/Province, OR, (b)(4)
USA

CONTACT: [REDACTED] (b)(4), (b)(6), (b)(7)(C) OR,
(b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-71XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

[(b)(4) Umatilla
County/Province, OR, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OR (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-71XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 10, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-71XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

January 10, 2001

01-016-22n

1. USDA Reference Number

2. Applicant Reference Number 2001-71XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-71XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID
2001-71XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, OR

DESTINATION:

HI, KS, MO, OR

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-71XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

CBI-DELETED

Monsanto Reference ID
2001-71XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

[CBI Deleted] -- Umatilla County/Province, OR, USA, 5 acres

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CBI-DELETED

Monsanto Reference ID

2001-71XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

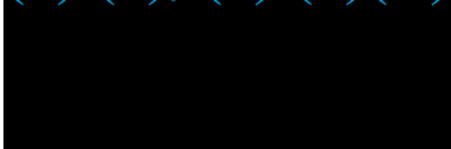
FAX (636) 737-7085

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 10, 2001

MONSANTO

Food · Health · Hope



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-71XRAB

January 10, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-016-22n

1. **USDA Reference Number**

2. **Applicant Reference Number** 2001-71XRAB

3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. **Duration of Introduction**

Interstate Movement and Release

February 09, 2001 - February 09, 2002

5. **Recipient**

Wheat, Triticum aestivum

6. **Regulated Article**

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID
2001-71XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-71XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, OR

DESTINATION:

HI, KS, MO, OR

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-71XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

CBI-DELETED

Monsanto Reference ID

2001-71XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (1)

OR

[CBI Deleted] -- Umatilla County/Province, OR, USA, 5 acres

MONSANTO

Food · Health · Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

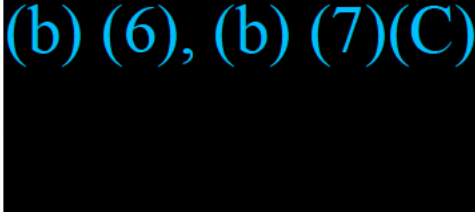
Monsanto Reference ID

2001-71XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 10, 2001

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-22n	Applicant #:	2001-71XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

ISJ

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006997

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-016-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-22n	Applicant #:	2001-71XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006998

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-22n	Applicant #:	2001-71XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

15
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006999

file copy

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

January 17, 2001

Dear Mr. Griesbach:

Enclosed is notification 01-016-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-22n	Applicant #:	2001-71XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 17, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-016-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-22n	Applicant #:	2001-71XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 15 February 2001

State: Hawaii

Rptloc01/R4.



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OR120018_BR_007001

FEB 16 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1516 Missouri Boulevard
Jefferson City, MO 65102

January 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-016-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-22n	Applicant #:	2001-71XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 01/31/01

State: MO

Rptloc01/R4

FEB 5 2001



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OR120018_BR_007002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

January 17, 2001

Dear Mr. Griesbach:

Enclosed is notification 01-016-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-016-22n	Applicant #:	2001-71XRAB
Received:	January 16, 2001	Effective:	February 15, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI KS MO OR		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

RECEIVED

JAN 24 2001

AGRICULTURE
PLANT DIVISION

STATE RESPONSE TO NOTIFICATION

✓*

State concurs with APHIS determination.

* See attached letter

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Daniel J. Hilburn

Signature:

(b) (6), (b) (7)(C)

Date:

2/14/01

State:

Oregon

Rptloc01/R4.



February 21, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release
Notification no. 01-016-22n (2001-71XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Oregon

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Oregon has (attached) conditions.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_007004

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
J. Griesbach, Oregon Dept. of Agric., Salem, OR
R. Stoaks, PPQ, WR, SCR, Sacramento, CA
File number 01-016-22n



Oregon

John A. Kitzhaber, M.D., Governor

Department of Agriculture

635 Capitol Street NE
Salem, OR 97301-2532

February 14, 2001



Mary Jackson
Biotechnology Program Operations
Permits and Risk Assessments
USDA, APHIS, PPQ
4700 River Road
Riverdale, MD 20737

Dear Ms. Jackson:

We have received and reviewed notification numbers 01-016-22n and 01-017-02n. These notifications were submitted by Monsanto for Glyphosate tolerant wheat. Due to an extremely sensitive market situation at the current time, we'd like to see stringent safeguards applied before this research proceeds in Oregon in 2001. We also suggest that given the current market climate around the world, USDA carefully review national requirements for research on genetically modified wheat. In particular, isolation distances designed to prevent mechanical mixing do not address pollen transfer concerns. Until tolerances for genetically modified wheat are established and accepted, protocols should reflect the need to ensure conventional wheat crops are completely free of contamination by genetically modified wheat.

Most of Oregon's wheat is grown for export and much of it goes to Japan. Since Japan will require mandatory labeling of genetically modified commodities in April of this year, it is extremely important that we ensure genetically modified wheat is fully segregated from Oregon's conventional commercial wheat crop. Inadvertent contamination of the conventional wheat crop would seriously constrain wheat grower's access to Japanese and other export markets. We suggest the following modifications to existing requirements to ensure that this 2001 research is done with the utmost concern for market preservation:

- 1.) Total acreage of plots is limited to 1.5 acres.
- 2.) Plots of genetically modified wheat must be separated from all other spring wheat by a distance of at least 660 ft.
- 3.) Plots of genetically modified wheat must be separated from non-spring wheat by a distance of at least 90 ft.
- 4.) Goatgrass (*Aegilops* sp.) must be eliminated from the area around the plots for a distance of at least 660 ft.
- 5.) Equipment used to plant and harvest the genetically modified wheat must be completely cleaned of all seeds and other plant parts on site before reuse.

6.) All parts of the genetically modified plants, including the seeds, must be destroyed on site. The plants must be sprayed with a labeled herbicide before plowing, flailing or other mechanical destruction.

7.) Plots must not be replanted into wheat in the year following planting of the genetically modified crop and the plots must be monitored for any volunteers. Volunteers must be destroyed.

8.) Either USDA must inspect the plots for isolation distance compliance and monitor the crop destruction process or the Oregon Department of Agriculture must be supplied with the information necessary to permit monitoring by ODA.

Thank you for helping us to make sure that this research does not interfere with the orderly marketing of Oregon's wheat crop. If you have any questions please don't hesitate to contact me.

Yours truly,

(b) (6), (b) (7)(C)

Daniel J. Hilburn
Administrator, Plant Division
(503) 986-4663

cc:

(b) (6), (b) (7)(C) Monsanto

MODE = MEMORY TRANSMISSION

START=FEB-23 16:04

END=FEB-23 16:14

FILE NO.=494

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	2	916367377005	004/004	00:06:17

***** -



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 21, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2001.

Interstate movement and Release
Notification no. 01-016-22n (2001-71XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Oregon

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Oregon has (attached) conditions.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_007008

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-016-22n Monsanto #2001-71XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2147303327

County
Umatilla County

State
OR

Umatilla County/OR (2147303327)

(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-016-22n Monsanto #2001-71XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147303327	Umatilla County	OR

Umatilla County/OR (2147303327)

Planting Date: 03/30/2001

Destruct Date: 06/18/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]